[Volume VI, Appx14199 – Appx24701]

Nos. 22-1972, -1973, -1975, -1976

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

MASIMO CORPORATION,

Appellant,

v.

APPLE INC.,

Appellee.

APPEAL FROM THE PATENT TRIAL AND APPEAL BOARD
CASE NOS. IPR2020-01713, IPR2020-01716, IPR2020-01733, IPR2020-01737

JOINT APPENDIX

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May 10, 2023

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE, INC., Petitioner,	)
	) IPR 2020-01716
-against-	) IPR 2020-01733
	) IPR 2020-01737
MASIMO CORPORATION, Patent Owner.	)

VIDEO-RECORDED DEPOSITION OF

THOMAS WILLIAM KENNY, JR. PH.D.

Zoom Recorded Videoconference

07/16/2021

9:03 a.m. (PDT)

REPORTED BY: AMANDA GORRONO, CLR

CLR NO. 052005-01

DIGITAL EVIDENCE GROUP

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as the context of this discussion.

Q. Well, let's start with the wristwatch-type structure we were discussing.

Do you agree in that context the light intensity taken by the photodiode increases roughly exponentially as the radial distance from the LEDs is increased?

A. I agree that it decreases. I think that is shown at the figure on the top of the next page right below this paragraph. I think that's well known. Whether it's exponentially or roughly exponentially or quadratically, you know -- but it does decrease and I think that's the key point.

Q. Do you agree the light intensity taken by the photodiode decreases as the radial distance from the LED is increased for any concentric array of detectors around a central LED?

A. We're talk about light exiting a central LED, going into tissue, bouncing around and then being captured by LEDs at various distances?

Q. Yes.

A. And with any specific kind of covers

or convex structures or windows, I think it would depend on some of those other details whether that was true.

But I think, in general, the intensity of the light that's reflected back towards the sensors decreases once you, once you move the distance away from the center.

Q. And you reference details such as convex structures. And we had a fair amount of discussion on that topic at your last deposition, correct?

A. We did. Yes.

And, Stephen, just to be clear --

Q. Yeah.

A. -- we're talking about the light that gets to the detectors. That would be affected by the things -- all the things in the path of the detector. The amount of light that's just being reflected backwards towards the detectors, I think, is understood to decrease as shown such as in this Figure 4 on the next page below this paragraph, as one moves away from the center.

the combination of Aizawa and Mendelson-2003.

I view Mendelson '799 as just part of the background information that explains that there are useful things you can do with that combination.

Q. Right. But you don't have any discussion of a motivation to combine Mendelson '799 with the other references in Paragraph 95 of your declarations or anywhere else, correct?

A. I think that's correct. The combination being described here is the combination of Aizawa and Mendelson-2003.

Q. Okay. So going back to Aizawa, Aizawa has a single concentric ring. If one were to add another ring of detectors, would that have resulted in a lower LED drive current to obtain the same amplitude signal?

MR. IN: Objection; form.

Q. Let me restate that.

If you're looking at Aizawa's ring of detectors, would adding more detectors to that existing ring result in a lower LED drive current to obtain the same amplitude signal as compared to

adding a new ring of detectors farther away from the central LED?

MR. IN: Same objection.

A. It's not really a hypothetical I've considered. So maybe just to make this clear. So, for example -- trying to maybe get to a particular case.

Looking at the figures below Paragraph 98. Not too far away hopefully. There we are.

So we're imagining the situation where there's the green inner ring is in place. And you're asking me to consider if I add detectors, what would be the relative effect of adding more to the green ring versus putting them out at the red ring, is that --

Q. Well, I think a better question -- so let's try this question first.

A. Okay.

Q. But if you start with Aizawa, a person of skill in the art is looking at Aizawa --

A. Okay.

Q. -- and, you know, you see there the signal concentric ring of detectors, correct, a person would see that.

And the person of skill in the art decided to add more detectors, would adding more detectors to the existing ring result in a lower LED drive current to obtain the same amplitude signal as opposed to adding a new ring of detectors farther away from the LED?

MR. IN: Objection; form.

Q. Let me try it -- no. Go ahead.

A. I mean, it's kind of there's some vagueness to this associated with, you know, for example in the Mendelson-2003 reference, the inner ring, which is six of their 2-by-3 millimeter photodetectors, there isn't room to add to that. So the next logical place would be a second ring. And that's what they've done.

Q. But if there is room to add, wouldn't the next logical place be the same ring?

A. I might do both. I think there's benefits of having more detectors. I think Mendelson

makes that clear. Even Aizawa makes that clear when it talks about going from three to four to eight. So I think in general there's benefits to more detectors. I, I -- more is better. And they're better in the inner ring and the outer ring.

Q. If you're looking at Aizawa's ring detectors, would adding more detectors to that existing ring result in being able to use a lower LED drive current to obtain the same amplitude signal as opposed to adding a new ring of detectors further away from the same LED?

MR. IN: Objection; argumentative. Form.

A. I mean, if the goal was only to produce the same likely waveform and do that with a reduction in the power from the LEDs, and you had room to put detectors into the system, I think we know from the discussion we've already had today, that there's more signal available in the region close to the center versus out at the end.

And let's maybe be specific here, there's a, there's a plot of the amplitude as a

function of separation in paragraph -- which we've been looking at also, you may find it before I do -- just before Paragraph 97.

Q. Yep.

A. There was -- the signal gets smaller as you go further away.

Q. Right.

If the goal was just to produce the same likely waveform and you could do that with reduction in power from the LEDs and you have detectors in the system, then the viable, sensible option is to add detectors to the existing ring; is that fair?

MR. IN: Objection; argumentative.

A. No, I would say it's a viable option. Another option is to add detectors to the second ring. You can -- as described in some of these other paragraphs, one can sum up the signals in parallel by wiring the detectors in parallel in the different rings and apply different amounts of gain so as to be able to recover amplitudes of the outer ring that are comparable to the amplitudes of the inner ring.

There may be benefits to sampling a larger portion of the tissue depending on the structure of the vessels and anatomy underneath the sensor.

Q. Is another option simply to make the existing detectors and the existing ring in Aizawa larger?

A. You know, I think Mendelson -- all of the Mendelson references, or many of them anyway, make prettily clear having a larger detector area is beneficial.

If you have the option, you know, given the configuration of the rest of the system to have larger area detectors and fill up more of the space, that would give you the opportunity to capture more light reflected back from the tissue. I think that's obvious to one of ordinary skill.

Q. So given all of these options, why would a person of skill in the art, starting with Aizawa, instead of adding detectors to the current ring or making those detectors larger, decide to add a whole 'nother ring and then separately wire the two

different rings in parallel?

MR. IN: Objection; form.

A. I think we've been over this. The second ring gives you the opportunity to capture more signal. Wiring them each ring in parallel an then processing them as described in the declaration gives you the opportunity to apply different amounts of gain to the processing of the inner and the outer ring so that the sum of those signals captures as much information as possible. A person of ordinary skill would consider combining these things in many ways including what is shown here.

Q. Would a person of skill in the art start with the simpler approach of simply adding detectors to the current ring or making those detectors larger?

MR. IN: Objection; argumentative.

A. You know, it would depend on the size and shape of the detectors, the overall size of the system, where are the opportunities to add detectors. One would consider those factors when making these decisions.

in what one of ordinary skill in the art would do as part of the routine examination of their options.

Q. Move the detector farther away from the LED require a higher drive current compared to an LED -- sorry, compared to a detector closer to the LED for a similar performance?

A. If nothing else mattered and all I'm asking is how do I get the same amount of photo current in a detector that's near versus far, I think the data here shows that the far detector has less signal available. This is this Figure 4 that we have in front of us. And so if you want to have the detector at the 8-millimeter position produce a reflected DC signal of 5 or so on the vertical axis, you would need to turn up the LED in order to get that particular circumstance to work out, yes.

Q. Let me ask you: Is there any reference that discusses the benefit of a second outside ring as opposed to a larger overall detection area?

MR. IN: Objection; form.

A. I think with respect to the Mendelson

a situation is detected, the oximeter has the ability to selectively disregard the readings obtained from the corresponding photodetectors. Otherwise, if the DC and AC signals measured for each photodetector in the array are similar in magnitude, which is an indication that the sensor is positioned over a homogenous area on the skin, the final computation...can be based on equal contributions from every photodetector in the array."

Sorry, that was a little longwinded, but it starts at the bottom of Column 12 and ends on the top of 13 and it's describing the benefit of having an inner and an outer ring that are separately processed.

Q. Isn't that discussing the measurement of each of the detectors individually?

A. That is right, it's measuring the signals from the inner ring and the outer ring and using them to make a decision about the quality of the situation. This is the benefit of having the second ring.

Q. So those photodetectors aren't wired

in parallel, correct?

A. Yeah, I think this just goes to the larger point that one of ordinary skill in the art is aware that it's possible to combine the signals from arrays of photodetectors in various ways, including wiring them in parallel or processing them separately. There's examples of circuits that do one or the other or both in the Declaration, a little further in. In this case, if the intent is to capture the signal from a specific sensor, then one would find a way to extract that signal, but it's also clear that if everything is done properly, then the final computation is based on equal contribution so there is a summing that takes place as part of this as well.

Q. In fact, it says -- going back to Column 12, this is Line 60, "Compare changes in the R/IR ratios obtained from each of the discrete photodiodes individually," correct?

Did I read that correctly?

A. Yes.

Q. So those photodetectors cannot be

wired in parallel, correct?

A. They, they can be wired in parallel at a later stage in the conditioning circuit. It depends on how and when the stages of this thing are assembled.

Q. This doesn't describe any benefit from having a first and second set of photodetectors that are each connected in parallel, correct?

In fact, it describes the opposite, correct, the benefit of monitoring individual detectors?

A. I don't believe those are mutually exclusive. There is a benefit in this case to monitoring them individually. I think it would be obvious that there would be a similar benefit if you gained up the rings separately and processed the ratio, but I think one of ordinary skill in the art would understand that within the conventional circuits for processing photodiode signals, one has the option to combine the signals and sum them up and then amplify. One has the option to amplify and then combine. One has the option to digitally convert all

of these signals and then do all of these manipulations in software. All of these are routinely available.

Q. I'm asking you -- well, it's not obvious that it's in the aggregate because Mendelson describes projecting individual signals, correct?

A. This section of Mendelson describes individual sensor signals.

Q. And I'm trying -- I guess this whole line of questioning, I'm asking you where in Mendelson '799, if anywhere, does it disclose the benefit of using parallel wiring of two rings of detectors?

For the record, you're reviewing Mendelson '799, correct?

A. That's correct.

Q. Can we agree that so far, I asked you to point me to where in Mendelson '799 there is a description of the benefit of two rings in detectors in parallel and so far you've pointed me to a portion of Mendelson that describes individual photodetectors not in parallel, correct?

MR. IN: Objection; argumentative.
A. It's describing the use of the signals from individual photodetectors. Whether they're summed in parallel later on is -- I think it's obvious that they are in Mendelson, but let me just continue browsing.
Q. So to make sure we're not wasting our time, I mean, the claim discusses photodiodes that are connected to one another in parallel so that's what we're looking for, right?
A. Uh-huh.
Q. You're discussing summing. I want to make sure we're on the same page.
A. Uh-huh. So summing and connecting parallel, you know, are just different ways of combining these signals, the one case after the initial digital conversion is taking place as described in some of the other references. Others could be done in hardware with discrete operational amplifiers and elements shown in the schematics that we've presented.
It's possible to do these

Filed August 10, 2021

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

IPR2020-01733
Patent 10,702,195

PATENT OWNER RESPONSE

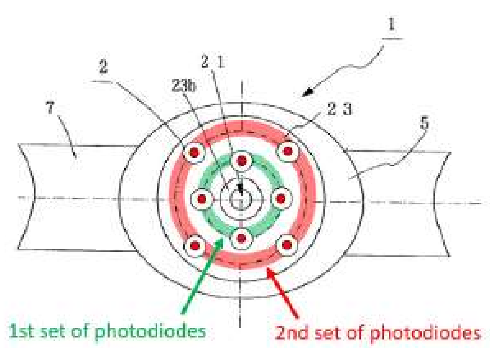
from a central emitter—would not provide the alleged benefits advanced by Petitioner. Indeed, Mendelson 2003 explains that a sensor would have a single signal stream in practice—not two different signal streams as claimed. Ex. 2004 ¶101.

1. <u>Petitioner's Proposed Combination Changes Aizawa's Principle Of Operation And Eliminates A Feature Aizawa Repeatedly Identifies As Important</u>

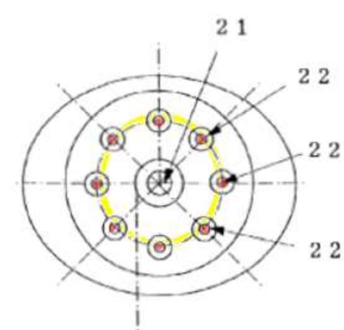
Aizawa's approach monitors different individual detector signals and calculates pulse rate based on each individual photodetector signal. *See* Ex. 1006 ¶[0028] (referencing Figure 3 and explaining the pulse rate calculation for "the photodetector"); *see also id.* ¶¶ [0019] ("diagram of ***a*** pulse wave which is the output of ***a*** photodetector"), [0023], [0028] ("amplifying the outputs of the photodetectors," and "comput[ing] the number of outputs above the threshold value per unit time so as to calculate a pulse rate"); Ex. 2004 ¶102; Ex. 2026 75:22-76:22. Aizawa does not measure aggregated signals from detectors connected in parallel. *Id.* Instead, Aizawa repeatedly highlights that measuring pulse using a single detector's output helps address sensor dislocation. Ex. 1006 ¶¶[0027]-[0029], [0032], [0036]; *see also id.* ¶[0007] (discussing prior art where if the "position is dislocated, no output can be obtained"). Dr. Kenny confirmed Aizawa can detect a pulse rate based on the signal from just one photodetector. Ex. 2026 79:22-80:3. Aizawa also emphasizes that the detectors—regardless of number—"should be disposed around the light

emitting diode 21 on a circle concentric to the light emitting diode 21 to detect a pulse wave." Ex. 1006 ¶[0032]; Ex. 2004 ¶102.

Petitioner ignores Aizawa's design and instead argues Mendelson 2003 would have motivated a POSITA to eliminate Aizawa's ability to monitor each detector individually by connecting the detectors in parallel, and add an additional ring of detectors to Aizawa's single symmetric ring. Pet. 16-22; *see also* 41-48. As shown below, Petitioner's combination adds "an additional ring of detectors to Aizawa, as per Mendelson-2003," resulting in eight total detectors. Pet. 21; Ex. 2004 ¶103.



Petitioner's illustration of its combination (Pet. 21)



Aizawa's illustrated detector arrangement (Ex. 1006 Fig. 4A)

Petitioner's modification relies on Mendelson 2003's two-ring test system to modify Aizawa into a dual-ring arrangement with one combined output signal for all four inner ring detectors and one combined output signal for all four outer ring detectors. Thus, Petitioner's modification changes the operation of Aizawa's pulse sensor in a way that eliminates Aizawa's ***core feature***—the ability to monitor pulse using the output of each ***individual*** detector, which Aizawa indicates avoids

Filed June 28, 2022

On behalf of:
Patent Owner Masimo Corporation
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.

Petitioner,

v.

MASIMO CORPORATION,

Patent Owner.

IPR2020-01733
U.S. Patent 10,702,195

PATENT OWNER'S NOTICE OF APPEAL TO THE U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Pursuant to 28 U.S.C. § 1295(a)(4)(A), 35 U.S.C. §§ 141(c), 142, and 319, 37 C.F.R. §§ 90.2(a) and 90.3, and Rule 4(a) of the Federal Rules of Appellate Procedure, Patent Owner Masimo Corporation ("Masimo") hereby appeals to the United States Court of Appeals for the Federal Circuit from the Judgment – Final Written Decision (Paper 33) entered on April 28, 2022 (Attachment A) and from all underlying orders, decisions, rulings, and opinions that are adverse to Masimo related thereto and included therein, including those within the Decision Granting Institution of *Inter Partes* Review, entered May 5, 2021 (Paper 7). Masimo appeals the Patent Trial and Appeal Board's determination that claims 1-17 of U.S. Patent 10,702,195 are unpatentable, and all other findings and determinations, including but not limited to claim construction, as well as all other issues decided adverse to Masimo's position or as to which Masimo is dissatisfied in IPR2020-01733 involving Patent 10,702,195.

Masimo is concurrently providing true and correct copies of this Notice of Appeal, along with the required fees, to the Director of the United States Patent and Trademark Office and the Clerk of the United States Court of Appeals for the Federal Circuit.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 28, 2022

/Jarom Kesler/
Jarom D. Kesler (Reg. No. 57,046)

Attorney for Patent Owner
Masimo Corporation

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Jeroen Poeze	Nonprovisional Application Number (if known):	Herewith
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

I. ☑ **<u>Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)</u>**

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, <u>or</u> the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ **<u>Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)</u>**

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Scott Cromar/	Date 2020-03-30
Name (Print/Typed) Scott Cromar	Practitioner Registration Number 65066

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☑ *Total of 1 forms are submitted.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in an interview with Scott Cromar on 05/20/2020. Amendments were made to cancel a set of claims and to correct the dependence of a remaining claim.

The application has been amended as follows:

Claims 17-29 were cancelled.

Claim 30, line 2, "24" was replaced by -- 31 --.

2. The following is an examiner's statement of reasons for allowance: The filed terminal disclaimer to co-pending application Nos. 16/829,510; 16/829,578; 16/834,536; 16/834,538; and 16/834,533 was approved on 05/06/2020 to resolve the provisional double patenting issues.

In regard to the related arts, Eastmond et al. (USPN 5,355,242 – applicant cited) teaches a device (Figs. 1 and 2A and associated descriptions) comprises: a first set of photodiodes (photodiodes in the first photodiode array 100, Figs. 1, 2A-1 and 2A-2), the

first set of photodiodes comprising at least four photodiodes (Figs. 1 and 2A-2), the photodiodes of the first set of photodiodes connected to one another in parallel (parallel, Col 2 lines 19-35) to provide a first signal stream responsive to light from at least one of the one or more light emitters (data outputs to element 102, Fig. 1 and associated descriptions); and a second set of photodiodes (photodiodes in the second photodiode array 101, Figs. 1, 2A-1 and 2A-2), the second set of photodiodes comprising at least four photodiodes (Figs. 1 and 2A-2), the photodiodes of the second set of photodiodes connected to one another in parallel (parallel, Col 2 lines 19-35) to provide a second signal stream responsive to light from at least one of the one or more light emitters (data outputs to element 103, Fig. 1 and associated descriptions) and a protrusion that extends over the photodiodes of the first and second sets of photodiodes (lens 200, Figs. 2A-1 and 2A-2 and associated descriptions; Col 3 lines 41-49). Chaiken et al. (USPN 6,223,063 – applicant cited) teaches an optical tissue modulation device (Figs. 1-3) comprises one or more emitter (Fig. 2) and four photodiodes disposed on a substrate (Fig. 1) and a cover with multiple protrusions placed on top of the photodiodes (Fig. 1). Kimura et al. (USPN 6,353,750 – applicant cited) teaches a noninvasive blood analyzer (Fig. 27) comprises one or more emitter (elements 11, Fig. 27), a photodiode array/ CCD (element 12, Fig. 27), and a cover with a protrusion (element 170, Fig. 27). Simonsen et al. (USPN 5,676,143 – applicant cited) teaches a glucose determination device (Figs. 15 and 21-22) comprises one or more emitters (emitters in Fig. 31), a first set of photodiodes, the first set of photodiodes comprising at least four photodiodes (row photodiodes 80a, Fig. 21), the photodiodes of the first set of photodiodes provides a first signal stream responsive to light from at least one of the one or more light

emitters attenuated by body tissue (row photodiodes 80a, Fig. 21 and implement the measuring functions of Fig. 15 and 20); and a second set of photodiodes, the second set of photodiodes comprising at least four photodiodes (row photodiodes 80b, Fig. 21), the photodiodes of the second set of photodiodes a second signal stream responsive to light from at least one of the one or more light emitters attenuated by body tissue (row photodiodes 80b, Fig. 21 and implement the measuring functions of Fig. 15 and 20). Wilcken et al. (USPN 7,230,227 – applicant cited) teaches a photodiode array (Figs. 1-5) comprises summing optical responses from multiple photodiodes, and the photodiodes of the first set of photodiodes connected to one another in parallel to provide a first signal stream responsive to light (Figs. 4-5). The teachings of Wilcken can be combined with the teachings of Simonsen in order to provide an alternative equivalent way to obtain the optical responses of the row photodiodes for glucose sensing.

3. However, the prior art of record does not teach or suggest “a first set of photodiodes positioned on a first surface and surrounded by a wall that is operably connected to the first surface, wherein: the first set of photodiodes comprises at least four photodiodes, and the photodiodes of the first set of photodiodes are connected to one another in parallel to provide a first signal stream; a second set of photodiodes positioned on the first surface and surrounded by the wall, wherein: the second set of photodiodes comprises at least four photodiodes, and the photodiodes of the second set of photodiodes are connected to one another in parallel to provide a second signal stream; and a cover located above the wall and comprising a single protruding convex surface configured to be located between tissue of the user and the first and second

sets of photodiodes when the physiological measurement device is worn by the user, wherein the physiological measurement device provides a plurality of optical paths, wherein each of the optical paths: exits an emitter of the one or more emitters, passes through tissue of the user, passes through the single protruding convex surface, and arrives at a corresponding photodiode of the at least one of the first or second sets of photodiodes, the corresponding photodiode configured to receive light emitted by the emitter after traversal by the light of a corresponding optical path of the plurality of optical paths and after attenuation of the light by tissue of the user", in combination with the other claimed elements/steps.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHU CHUAN LIU whose telephone number is (571)270-5507. The examiner can normally be reached on M-Th (8am-6pm).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Cheng can be reached on (571) 272-5596. The fax phone

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Poeze et al.	
U.S. Patent No.:	10,702,195	Attorney Docket No.: 50095-0026IP1
Issue Date:	July 7, 2020	
Appl. Serial No.:	16/834,467	
Filing Date:	March 30, 2020	
Title:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	

DECLARATION OF DR. THOMAS W. KENNY

Declaration

I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable under Section 1001 of Title 18 of the United States Code.

By: ______________________________

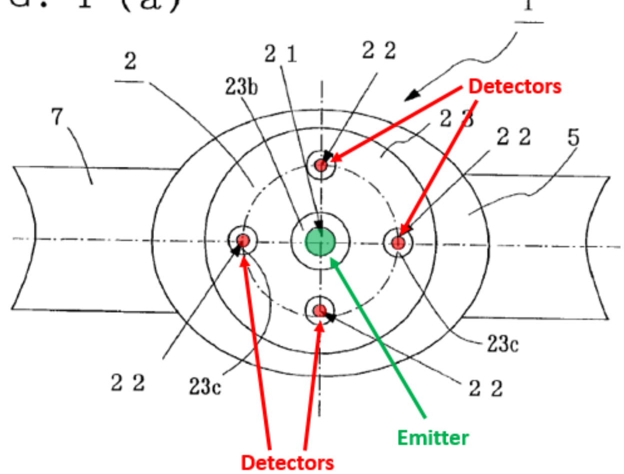
Thomas W. Kenny, Ph.D.

67. A POSITA would have been able and motivated to combine Aizawa, Mendelson-2003, Ohsaki, and Goldsmith in the manner described below to derive various benefits.

Aizawa + Mendelson-2003

68. As I described above in Section VII.A, Aizawa teaches a first set of photodiodes in the form of four photodetectors 22 that are circularly arranged around a centrally located emitter, as shown below. APPLE-1006, [0023]. Moreover, a signal stream from this first set of photodiodes is sent to a drive detection circuit 24 that "amplif[ies] the outputs of the photodetectors." *Id.*

FIG. 1 (a)



APPLE-1006, FIG. 1(a)

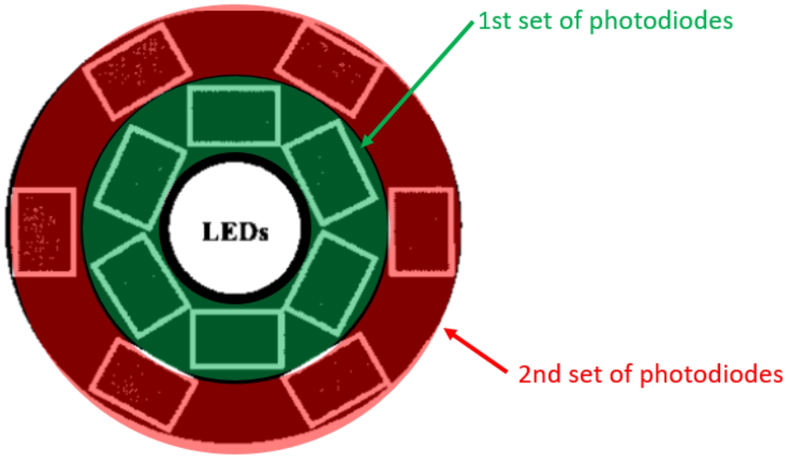
69. Aizawa teaches that 8 or more photodetectors may be provided to improve detection efficiency in some cases. *Id.*, [0032].

70. Aizawa does not expressly teach a second set of photodiodes that are connected to one another in parallel to provide a second signal stream as recited in

claim 1 of the '195 patent. That is, while Aizawa teaches various ways of using a single ring of multiple detectors to improve detection efficiency, it does not explicitly mention that these multiple detectors may be provided as first and second sets of photodiodes that are each connected in parallel and provide first and second signal streams, respectively. APPLE-1006, [0013], [0030], [0032]. However, a POSITA would have realized that the arrangement of Aizawa's multiple detectors—which are arranged along a single ring—can be modified in view of Mendelson-2003 to be instead arranged along two rings to provide a wider detection area, thereby further advancing Aizawa's goal of improving detection efficiency through increased power savings as taught by Mendelson-2003. APPLE-1006, [0013], [0030], [0032]; APPLE-1024, 3017, 3019.

71. For example, as I show below, Mendelson-2003 teaches using two rings of photodiodes/detectors ("near positioned" detectors highlighted in green, and "far positioned" detectors highlighted in red) where the detectors in each of the near and far rings are "***wired in parallel*** and connected through a central hub to the common summing input of a current-to-voltage converter." APPLE-1024, 3017. Mendelson-2003 further teaches that this configuration "widen[s] the active area of the PD which helps to collect a bigger portion of backscattered light intensity," thereby improving the light collection efficiency *Id.*, 3019. This configuration

thus allows additional light to be captured, which in turn allows a lower brightness of LEDs to be used, which in turn would consume less power.



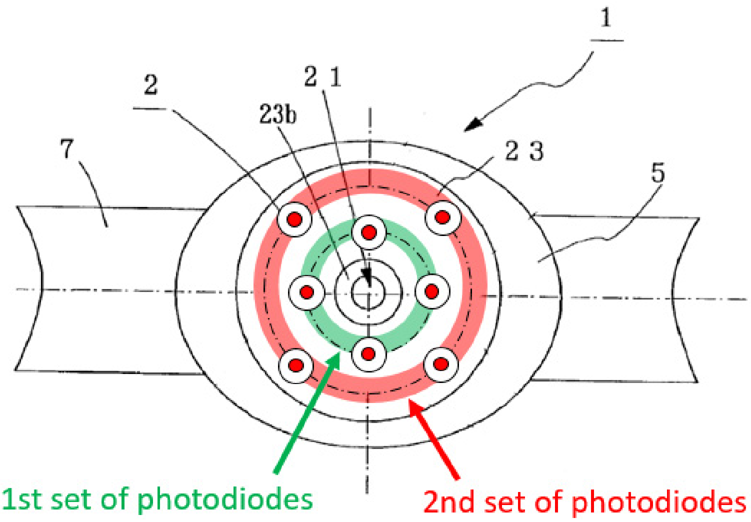
APPLE-1024, FIG. 1

72. Moreover, Mendelson-2003 is aimed at modifying conventional PD arrangements—***like that disclosed in Aizawa where a single ring of multiple PDs are mounted symmetrically around a light source***—to use two distinct rings of PDs that are mounted symmetrically around the light source. *See* APPLE-1024, 3016 (referring to conventional sensor designs based on "radial arrangement" of PDs or LEDs). Indeed, the prior art references mentioned in Mendelson-2003—*i.e.*, references [1]-[5]—describe conventional single ring devices such as those found in Mendelson-1988 (which corresponds to reference) and Aizawa. *See* APPLE-1015, 168, FIG. 2(A); APPLE-1006, [0032]. Mendelson-2003's 2-ring configuration thus allows additional light to be captured, which enables use of

lower brightness LEDs (*i.e.*, LEDs driven by a lower driving current) while still achieving acceptable signals from the PDs. APPLE-1024, 3017, 3019.

73. A POSITA in possession of both Aizawa and Mendelson-2003 would have recognized Mendelson-2003's use of two concentric rings (one that is near-positioned and another that is far-positioned) of photodiodes as a desirable detector configuration that would reap similar benefits for Aizawa in terms of achieving "power savings in the design of a more efficient" pulse sensing device. APPLE-1024, 3017. By using Mendelson-2003's power-saving (*i.e.*, efficiency-enhancing) PD configuration, the power consumption of a wrist-based pulse sensing device as in Aizawa can be reduced through use of a less bright and, hence, lower power-consuming LED. This would in turn allow Aizawa's wrist-based device to have a longer battery life. *Id.*

74. An example implementation of adding an additional ring of detectors to Aizawa, as per the teachings of Mendelson-2003, is shown below:



APPLE-1006, FIG. 1(a)

75. A POSITA would have further realized, in view of Mendelson-2003, that such a two-ring arrangement can be implemented in a wrist sensor device as in Aizawa by wiring each ring of detectors in parallel and summing the input of their respective streams. APPLE-1024, 3017; *see also* APPLE-1042, 5:20-67, FIGS 1-2; APPLE-1025, 4:23-30.

76. A POSITA also would have found it obvious to modify Aizawa with Mendelson-2003 to add an additional ring of detectors because doing so merely involves the use of known solutions to improve similar systems and methods in the same way. For instance, a POSITA would have recognized that applying Mendelson-2003's teachings regarding two, concentric rings of detectors that are each connected in parallel to Aizawa's sensor would have led to predictable results without significantly altering or hindering the functions performed by Aizawa's

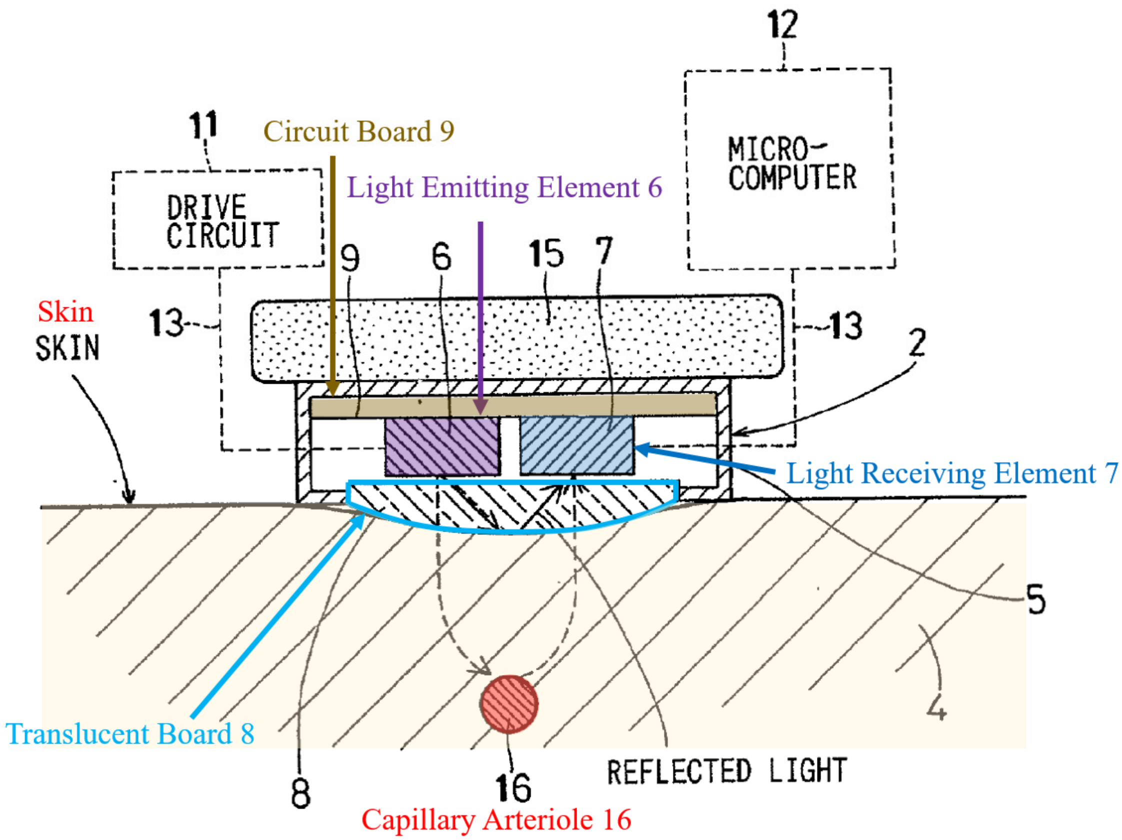
sensor. A POSITA would have been motivated to provide the well-known feature of providing multiple rings of emitters to a pulse sensor to achieve the predictable benefits offered by Mendelson-2003's description of the same. In fact, Aizawa itself contemplates, and is thus capable of supporting, the addition of extra detectors to improve light collection efficiency, although it does not disclose whether they may be arranged as two concentric rings. APPLE-1006, [0032]. Moreover, as noted above, Mendelson-2003 expressly contemplates adding an additional ring of detectors to a conventional 1-ring PD arrangement precisely as found in Aizawa. APPLE-1024, 3016.

<u>Aizawa + Mendelson-2003 + Ohsaki</u>

77. A POSITA would have been able and motivated to *further* combine the teachings of Aizawa-Mendelson-2003 with the teachings of Ohsaki such that the cover of Aizawa-Mendelson-2003's wrist-worn sensor would include a convex surface, improving adhesion between a subject's wrist and a surface of the sensor. APPLE-1014, [0025] (the convex surface prevents slippage of the detecting element from its position on the subject's wrist, and the convex nature of the surface suppresses the "variation of the amount of the reflected light" that reaches the detecting element).

78. In particular, Ohsaki describes a “detecting element” that includes “a package 5, a light emitting element 6 (e.g., LED), a light receiving element 7 (e.g., PD), and a translucent board 8.” APPLE-1014, [0017]. “The package 5 has an opening and includes a” substrate in the form of “circuit board 9,” on which light emitting element 6 and light receiving element 7 are arranged. *Id.*. As I show below in Ohsaki’s FIG. 2, translucent board 8 is arranged such that, when the sensor is worn “on the user’s wrist … the convex surface of the translucent board … is in intimate contact with the surface of the user’s skin”; this contact between the convex surface and the user’s skin is said to prevent slippage, which increases the strength of the signals obtainable by Ohsaki’s sensor. APPLE-1014, [0015], [0017], [0025], FIGS. 1, 2, 4A, 4B.

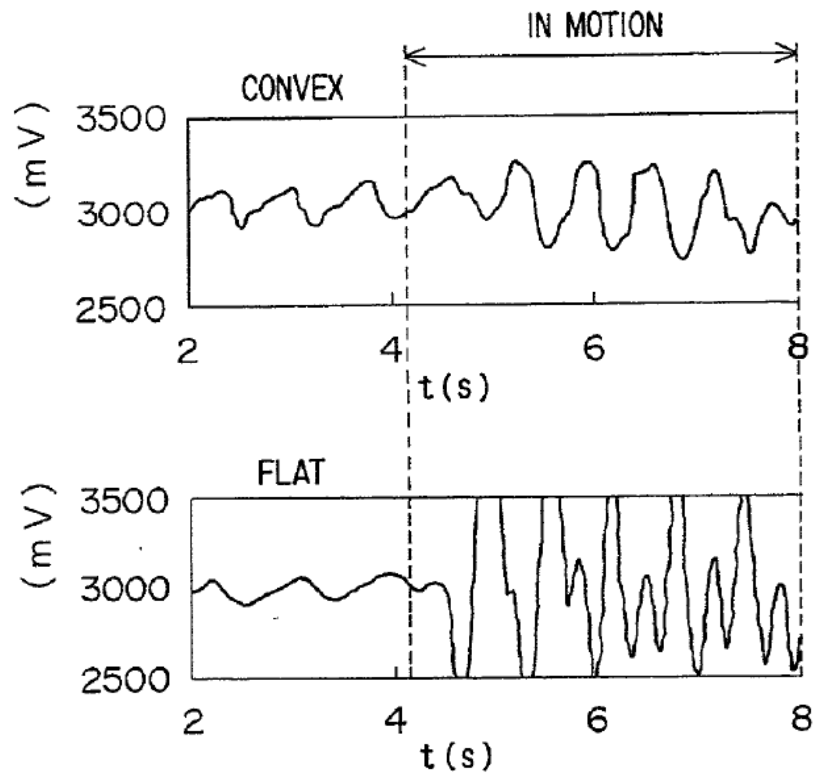
FIG. 2



APPLE-1014, FIG. 2 (annotated)

79. Here, Ohsaki explains that "if the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist as shown in FIG. 4B (reproduced below)," but that if "the translucent board 8 has a convex surface…variation of the amount of the reflected light…that reaches the light receiving element 7 is suppressed." APPLE-1014, [0025]. The convex surface is also said to prevent "disturbance light from the outside" from penetrating translucent board 8. *Id*. Thus, when a convex cover is used, "the pulse wave can

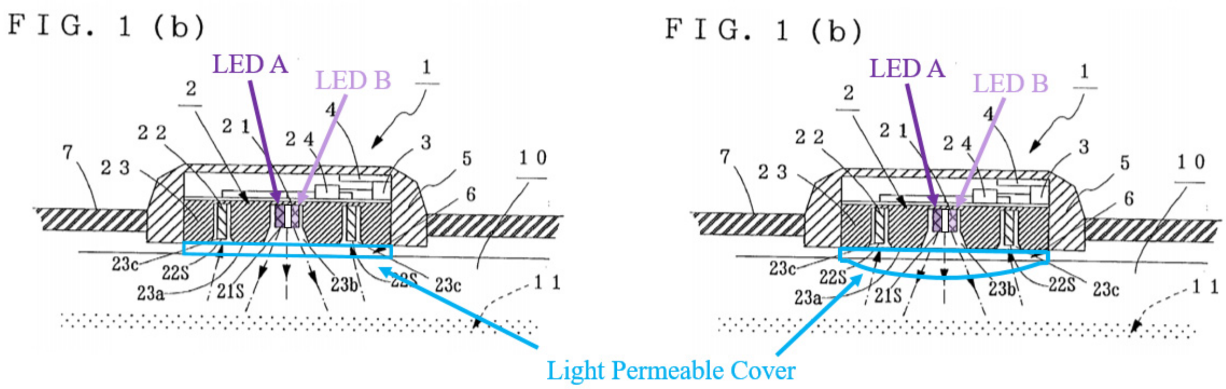
be detected without being affected by the movement of the user's wrist 4 as shown in FIG. 4A." *Id.*



APPLE-1014, FIGS. 4A, 4B

80. Thus, as I show below, a POSITA would have found it obvious to modify the sensor's flat cover (left) to include a lens/protrusion (right), similar to Ohsaki's translucent board 8, so as to improve adhesion between the user's wrist and the sensor's surface, improve detection efficiency, and protect the elements within the sensor housing. APPLE-1014, [0025] (explaining that the convex surface of translucent board 8 prevents slippage of a detecting element from its position on

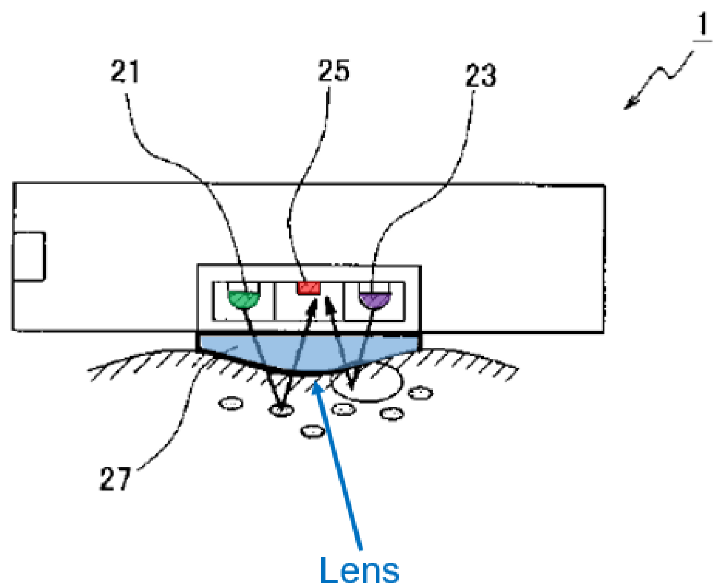
the wrist, and suppresses the "variation of the amount of the reflected light" that reaches the detecting element).



APPLE-1006, FIG. 1(b)

81. A POSITA would have combined the teachings of Aizawa-Mendelson-2003 and Ohsaki as doing so would have amounted to nothing more than the use of a known technique to improve similar devices in the same way. For instance, a POSITA would have recognized that incorporating Ohsaki's convex surface is simply improving Aizawa-Mendelson-2003's transparent plate 6 that has a flat surface to improve adhesion to a subject's skin and reduce variation in the signals detected by the sensor. Furthermore, the elements of the combined system would each perform similar functions they had been known to perform prior to the combination. That is, Aizawa-Mendelson-2003's transparent plate 6 would remain in the same position, performing the same function, but with a convex surface as taught by Ohsaki.

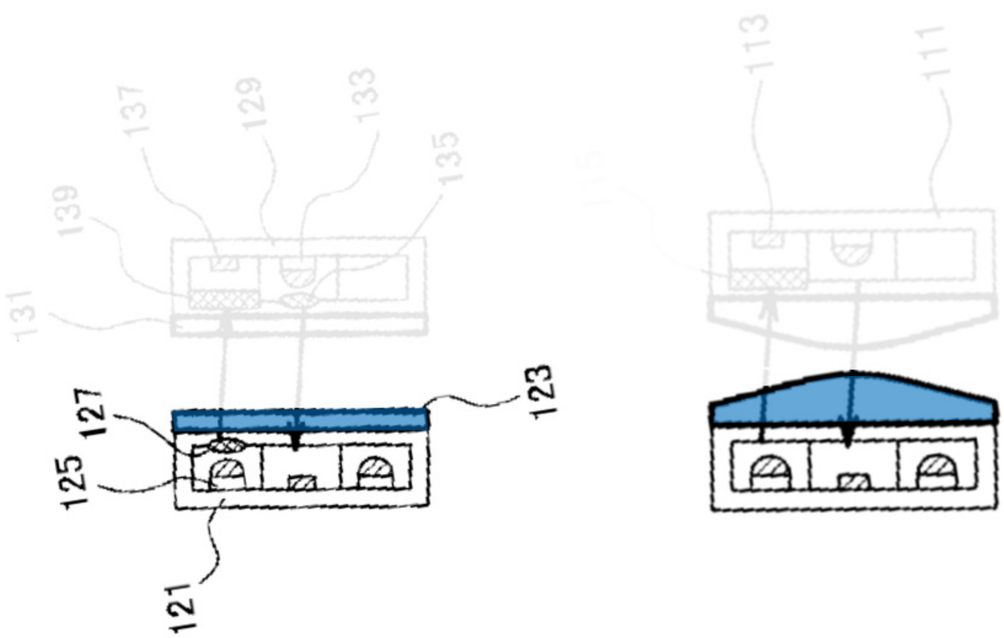
82. Incidentally, Inokawa provides further rationale for a POSITA to modify Aizawa to include a cover comprising a protruding convex surface, thus further strengthening the combination I just described above. For example, as shown below, Inokawa discloses a side lens 27:



APPLE-1008, FIG. 2

83. Inokawa further teaches that the "lens makes it possible to increase the light-gathering ability of the LED." APPLE-1008, [0015]. Thus, a POSITA would have understood that adding a protruded convex surface to Aizawa would have the additional benefit of increasing light collection efficiency, which would in turn lead to an improved signal-to-noise ratio and more reliable pulse detection. The lens of Inokawa provides precisely such an additional benefit to Aizawa's device by refracting/concentrating incoming light signals reflected by the blood. *Id.*

84. A POSITA would have further understood, in view of Inokawa, *how* to implement the convex surface of Ohsaki into Aizawa. For example, as shown below, Inokawa teaches that its cover may be either flat (left) such that "the surface is less prone to scratches," Inokawa at [0106], or in the form of a lens (right) to "increase the light-gathering ability of the LED." APPLE-1008, [0015].



APPLE-1008, FIG. 17 (left), FIG. 16 (right)

85. A POSITA would have further recognized that the transparent acrylic material used to make Aizawa's plate can be readily formed to have a convex shape as in Inokawa. *See* APPLE-1009 at 3:46-51, FIG. 1.

<u>Aizawa + Mendelson-2003 + Ohsaki + Goldsmith</u>

Date, and there was nothing new or inventive about changing the way such photodiodes are connected. *See* APPLE-1025, 4:23-30.

107. Moreover, a POSITA would have recognized that there can be multiple benefits to separately transmitting signals streams from the near and far detectors—as opposed to combining all the signals from the detectors into a single stream. For example, Mendelson '799 teaches that the detected values from each of its near and far detector arrays can be monitored such that "if both of them are not in the mentioned range, a corresponding alarm is generated indicative of that the sensor position should be adjusted." APPLE-1025, 13:19-30, FIG. 10A. In other words, monitoring each signal stream (from each ring of detectors) separately allows the system to determine when the sensor device is so severely located that its position should be adjusted. Mendelson '799 also teaches that its detector configuration can help detect "movement/breathing artifacts" and subsequently generate "a corresponding alarm signal." APPLE-1025, 13:31-42. Mendelson '799 is able to achieve this (along with other benefits) by maintaining separate streams coming from each of its inner and outer rings of photodetectors. *Id.* Having two separate signal streams can also offer various advantages during research, testing, and/or calibration scenarios, where the ability to monitor each stream separately can be beneficial, for instance, to ensure that both rings are performing properly.

108. Additionally, a POSITA would have known that "[t]he intensity of the backscattered light decreases in direct proportion to the square of the distance between the photodetector and the LEDs." APPLE-1015, 168. In other words, a POSITA would have recognized that the photodiodes in the far ring (*i.e.,* second set of photodiodes) would receive reflected light having a lower intensity than that received by the photodiodes in the near ring (*i.e.*, first set of photodiodes) and would have been motivated and found it obvious to account for this discrepancy. Indeed, as shown in the plot below, "the light intensity detected by the photodiode decreases roughly exponentially as the radial distance from the LED's is increased." APPLE-1017, 801. This is because "the probability that the incident photons will be absorbed as they traverse a relatively longer path length before reaching the detector is increased." *Id.*

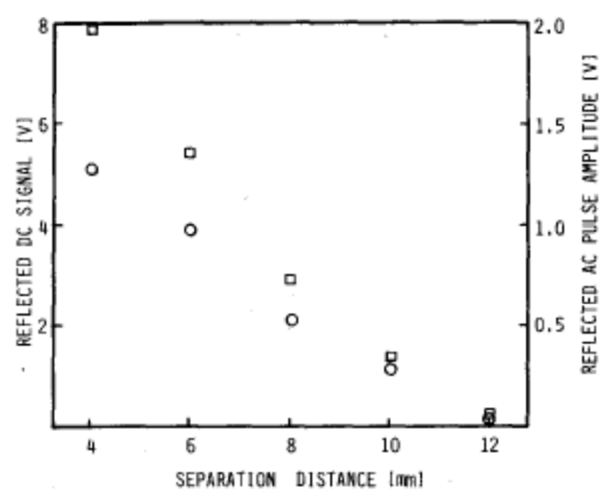


Fig. 4. The effect of LED/photodiode separation on the dc (□) and ac (○) components of the reflected infrared photoplethysmograms. Measurements were performed at a skin temperature of 43°C.

APPLE-1017, FIG. 4.

109. In Aizawa, a "drive detection circuit 24" is used for "amplifying the outputs of the photodetectors" and transmitting the amplified data to the arithmetic circuit 3, which computes the pulse rate. APPLE-1006, [0023], [0028]. In the modified Aizawa-Mendelson-2003 system, a POSITA would have recognized that the inner ring is likely to produce far greater currents compared to the outer ring due to the above-noted exponential relationship between detected light intensity and distance from the LED. APPLE-1017, 801. To ensure that the pulse rate data provided by the outer ring is preserved when combined with the pulse rate data provided by the inner ring, a POSITA would have found it obvious, in some implementations, to keep each ring separately wired and connected to its own amplifier (*i.e.*, drive detection circuit 24) to thereby keep the magnitude of the current signals provided by each ring approximately the same before being combined and transmitted to the arithmetic circuit 3. Otherwise, if all the photodiodes in both the first and second rings in the modified Aizawa's sensor device are connected together in parallel such that a single stream is output (from both rings) to a single amplifier, signals detected by the near/first sets of detectors may drown out the weaker signals coming from the far/second sets of detectors, thereby diminishing the enhanced sensitivity and collection efficiency achieved through the widened detection area.

[1e]: a second set of photodiodes positioned on the first surface and surrounded by the wall, wherein:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Poeze et al.	
U.S. Patent No.:	10,702,195	Attorney Docket No.: 50095-0026IP1
Issue Date:	July 7, 2020	
Appl. Serial No.:	16/834,467	
Filing Date:	Mar. 30, 2020	
Title:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	

SECOND DECLARATION OF DR. THOMAS W. KENNY

I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of the Title 18 of the United States Code.

Dated: November 7, 2021 By: ________________________

Thomas W. Kenny, Ph.D.

experience, including my work experience in the fields of mechanical engineering, computer science, biomedical engineering, and electrical engineer; my experience in teaching those subjects; and my experience in working with others involved in those fields. In addition, I have analyzed various publications and materials, in addition to other materials I cite in my declaration.

6. My opinions, as explained below, are based on my education, experience, and expertise in the fields relating to the ’195 Patent. Unless otherwise stated, my testimony below refers to the knowledge of one of ordinary skill in the fields as of the Critical Date, or before.

II. Ground 1

7. As I explained at length in my first declaration, a POSITA “would have found it obvious to modify the [Aizawa] sensor’s flat cover…to include a lens/protrusion…similar to Ohsaki’s translucent board 8, so as to [1] improve adhesion between the user’s wrist and the sensor’s surface, [2] improve detection efficiency, [3] and protect the elements within the sensor housing.” APPLE-1003, ¶¶80-85. Rather than attempting to rebut my testimony on these points, Masimo and its witness, Dr. Madisetti, responded with arguments that are technically and factually flawed.

8. Specifically, Masimo contends that “Ohsaki and Aizawa employ different sensor structures (rectangular versus circular) for different measurement locations (back side versus palm side of the wrist), using different sensor surface shapes (convex versus flat) that are tailored to those specific measurement locations” and from this concludes that “[a]

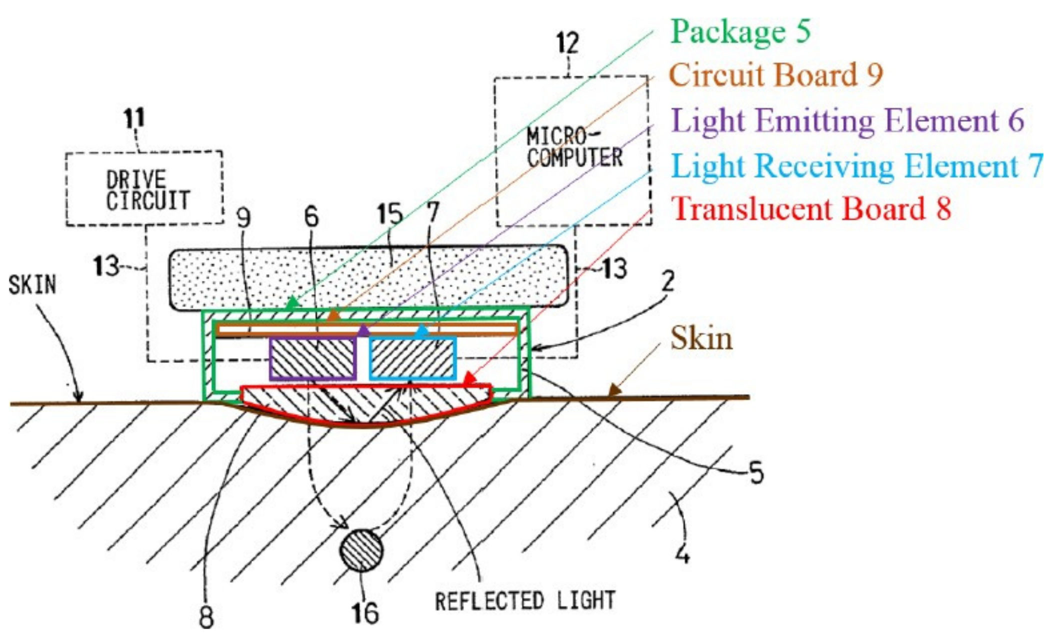
POSITA would [not] have been motivated to combine the references and reasonably expected such a combination to be successful." IPR2020-01733, Pap. 15 ("**POR**"), 1-3.

9. In this way and as I explain in further detail, the POR avoids addressing the merits of the combinations advanced in Apple's Petition, relies on mischaracterizing the prior art combinations and my testimony, and ignores the inferences and creative steps that a POSITA would have taken when modifying Aizawa's sensor to achieve the benefits taught by Ohsaki and Mendelson-2003, among others.

10. Contrary to Masimo's contentions, Ohsaki does not limit its benefits to a rectangular sensor applied to a particular body location, and a POSITA would not have understood those benefits as being so limited. For example, Ohsaki teaches that "the detecting element and the sensor body 3 may be worn on the back side of the user's forearm" or wrist. Nowhere does Ohsaki teach that its sensor can only be worn on a particular body location. APPLE-1014, [0030], [0008]-[0010], Abstract. In its summary of invention and claim preambles, Ohsaki explains that the object of its invention is "to provide a human pulse wave sensor which is capable of detecting the pulse wave ***of a human body*** stably and has high detection probability." APPLE-1014, [0007], claims 1-8. Thus, Ohsaki's disclosure should not be narrowly understood as applying to a single location or a single embodiment. Aizawa similarly reveals an embodiment in which its sensor is located on the palm side of the wrist (*see* APPLE-1006, FIG. 2, [0002], [0009]), but does not limit its sensor to being applied to just the palm side of the wrist. A POSITA, based on Aizawa and Ohsaki's disclosure, would have understood that the sensors in Aizawa and Ohsaki, when combined

in the manner explained in my earlier declaration, would have been applicable to various locations on a human body and would have improved the performance of the sensor by providing the benefits described in these disclosures. Indeed, a POSITA would understand that the claimed benefits of the detector arrangement and the convex cover would have been useful and beneficial for measurements on many other locations.

11. In addition to the above, as shown in Ohsaki's FIG. 2 (reproduced below), Ohsaki attributes the reduction of slippage afforded by use of translucent board 8 (and additional related improvements in signal quality) to the fact that "***the convex surface of the translucent board…is in intimate contact with the surface of the user's skin***"[1] when the sensor is worn. APPLE-1003, ¶78; APPLE-1014, [0015], [0017], [0025], FIGS. 1, 2, 4A, 4B.



APPLE-1014, FIG. 2 (annotated).

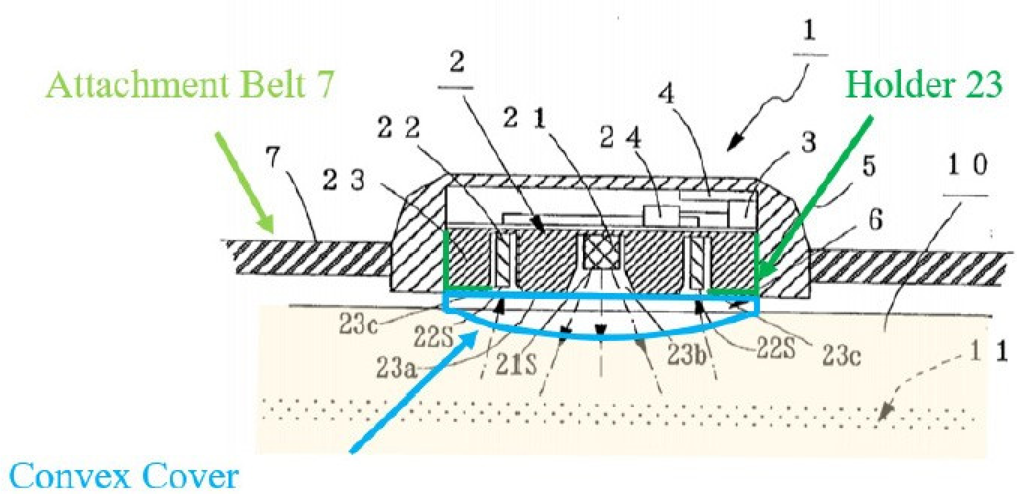
[1] Unless otherwise noted, emphases in quotations throughout my declaration are added.

12. Notably absent from Ohsaki's discussion of these benefits is any mention or suggestion that they relate to the shape of the perimeter of translucent board 8 (whether circular, rectangular, ovoid, or other). Rather, when describing the advantages associated with translucent board 8, Ohsaki contrasts a "convex detecting surface" from a "flat detecting surface," and explains that "if the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist," but that ***if the board "has a convex surface…variation of the amount of the reflected light…that reaches the light receiving element 7 is suppressed***." APPLE-1003, ¶79; APPLE-1014, [0015], [0025].

13. From this and related description, a POSITA would have understood that a protruding convex cover would reduce the adverse effects of user movement on signals obtainable by photodetectors which are positioned to detect light reflected from user tissue. APPLE-1003, ¶¶79-81; APPLE-1014, [0015], [0017], [0025], FIGS. 1, 2, 4A, 4B; *see also* APPLE-1006, [0012], [0013], [0023], [0024], [0026], [0030], [0034], FIGS. 1(a), 1(b). A POSITA would expect that these benefits would apply to the pulse wave sensor of Aizawa, as well as to other wearable physiological monitors.

14. In addition, as I explain with respect to the prior art figures reproduced below, the POSITA would have found it obvious to improve Aizawa's sensor based on Ohsaki's teachings, and would have been fully capable of making any inferences and creative steps necessary to achieve the benefits obtainable by modifying Aizawa's cover to feature a

convex detecting surface.[2] *See also* APPLE-1008, ¶¶14-15, FIG. 1. The following annotated FIG. 1(b) from Aizawa shows the results of the proposed combination:



APPLE-1006, FIG. 1(b)(annotated)

15. And, contrary to Masimo's contentions, the POSITA would have in no way been dissuaded from achieving those benefits by a specific body location associated with Ohsaki's sensor. POR, 32-38. Indeed, a POSITA would have understood that a light permeable convex cover would have provided improved adhesion as described by Ohsaki in a sensor placed, for example, on the palm side of the wrist or other locations on the body. APPLE-1014, [0025], Claim 3 (stating that "the detecting element is constructed to be worn on a user's wrist or a user's forearm" without specifying a back or front of the wrist or forearm), FIGS 4A, 4B; *see also* APPLE-1063, 91.

16. A POSITA would also have understood that certain locations present anatomical

[2] Nowhere in Ohsaki is the cover depicted or described as rectangular. APPLE-1014, [0001]-[0030]; FIGS. 1, 2, 3A, 3B, 4A, 4B.

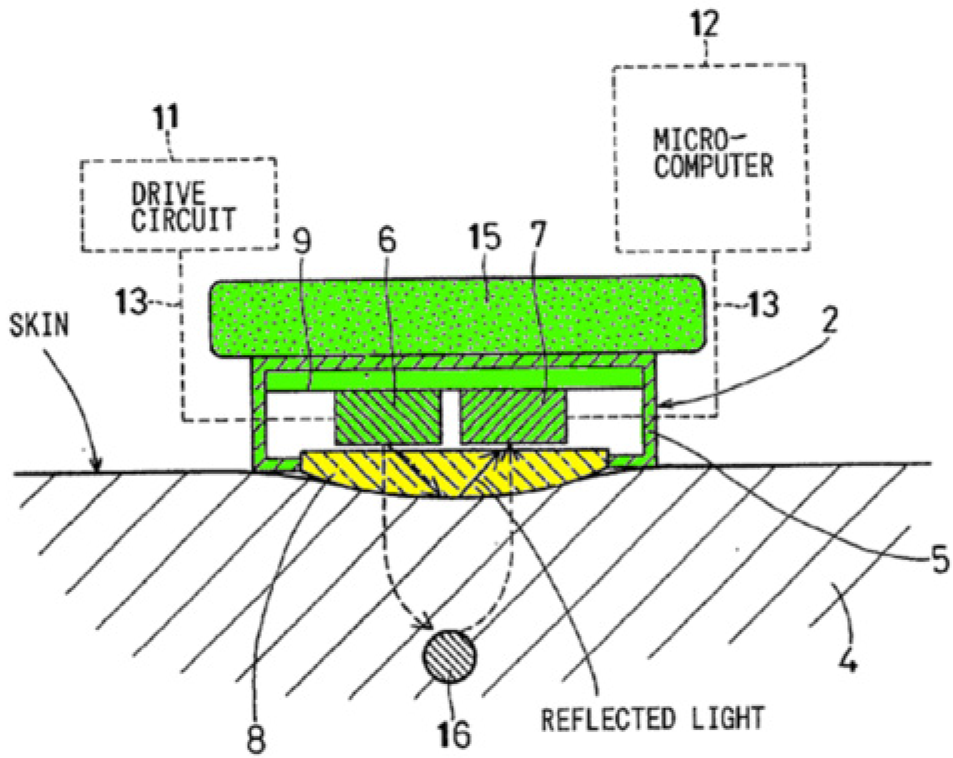
features that provide for easy measurement of large reflected light signals and other locations present anatomical features that reduce the amplitude of the reflected light signals. Because of this, a POSITA would be motivated to search for features from other references that can provide improved adhesion, improved light gathering, reduced leakage of light from external sources, and protection of the elements within the system in order to successfully detect a pulse wave signal from many locations.

17. For these and other reasons explained below, Masimo's arguments should be rejected. The sections below address the arguments with respect to Ground 1 presented in Masimo's POR and explain, in more detail, why those arguments fail.

A. Ohsaki does not teach or require that its translucent board 8 is "rectangular" in shape

18. In my first declaration, I explained that a POSITA would have modified Aizawa in view of Ohsaki such that Aizawa's cover "would include a convex surface, improving adhesion between a subject's wrist and a surface of the sensor." APPLE-1003, ¶¶77-81 (citing APPLE 1009, [0025] Ohsaki explains that the "convex surface of the translucent board 8" is responsible for this improved adhesion). Masimo argues that it is not the "convex surface" that improves adhesion in Ohsaki, but instead the "longitudinal shape" of "Ohsaki's translucent board [8]." *See* POR, 12, 23-29 (citing APPLE-1014, [0019]). However, the portion of Ohsaki cited does not include any reference to board 8. *See* APPLE-1014, [0019]. Ohsaki does ascribe a "longitudinal" shape to a different component: "detecting element 2." *See id.* Ohsaki never describes the "translucent board 8" as "longitudinal," and nowhere describes "translucent board 8" and "detecting element

2" as having the same shape. *See generally* APPLE-1014. In fact, as illustrated in Ohsaki's FIG. 2 (reproduced below), translucent board 8 (annotated yellow) is not coextensive with the entire tissue-facing side of detecting element 2 (annotated green).

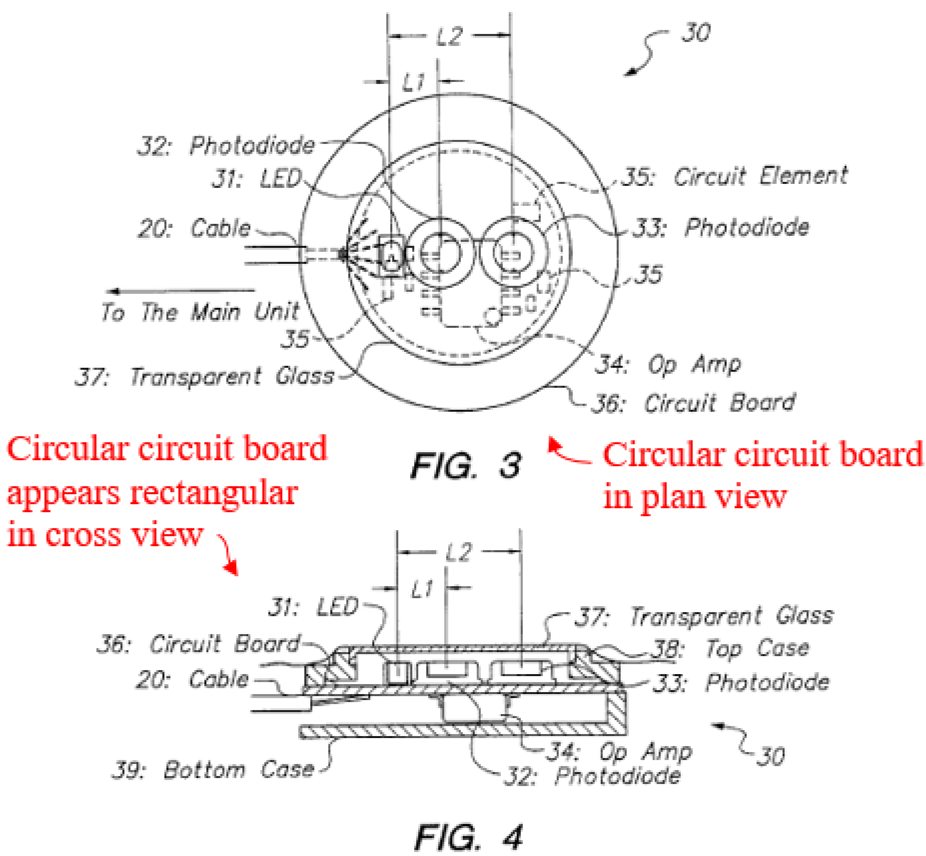


APPLE-1014, FIG. 2 (annotated)

19. Based on the unsupported contention that translucent board 8 has a "very pronounced longitudinal directionality," Masimo concludes that the translucent board 8 has a "rectangular" shape that is allegedly incompatible with Aizawa. But Ohsaki never describes translucent board 8, or any other component, as "rectangular"; in fact, the words "rectangular" and "rectangle" do not appear in Ohsaki's disclosure. *See generally* APPLE-1014.

20. Indeed, the POR incorrectly assumes that because Ohsaki's light emitting element

and the light receiving element are arranged in a longitudinal structure, Ohsaki's translucent board must have a rectangular structure. APPLE-1014, [0009], [0019]; POR, 16-17. Yet a POSITA would have known and understood that an elliptical or circular sensor or board configuration can also have a longitudinal structure or appearance under a cross-sectional view. An example illustrating such an understanding, ***contrary to POR's flawed assumption***, is shown below in US Patent No. 6,198,951 ("Kosuda")'s FIGS. 3 and 4. APPLE-1010, 8:42-56.



APPLE-1010, FIGS 3 and 4

21. Attempting to confirm its false conclusion, Masimo asserts that "***Ohsaki illustrates two cross-sectional views*** of its board that confirm it is rectangular." POR, 16 (citing Ex. 2004, [36]-[39]). Masimo identifies these "two cross-sectional views" as FIGS. 1 and 2,

and infers the supposed "rectangular shape" of the translucent board 8 based on FIG. 1 showing the "short" side of the device, and FIG. 2 showing the "long" side of the same device. *See* POR, 16-18. But, according to Ohsaki, FIG. 2 is "a schematic diagram," not a cross-sectional view, and Ohsaki never specifies that FIGS. 1 and 2 are different views of the same device. APPLE-1014, [0013]. Accordingly, nothing in Ohsaki supports Masimo's inference that the "translucent board 8" ***must be*** "rectangular" in shape. *See, e.g.,* APPLE-1014, [0013], [0019], [0025], FIG. 2. Further, even if it is possible for the translucent board 8 to be "rectangular," Ohsaki certainly does not teach nor include any disclosure "***requiring***" this particular shape. *Id.*

22. The POR presents multiple arguments with respect to Ground 1 that are premised on Ohsaki ***requiring*** the translucent board 8 to be "rectangular." Because Ohsaki discloses no such shape for the translucent board 8, these arguments fail.

23. In addition, as discussed above, even if Ohsaki's translucent board 8 were somehow understood to be rectangular, a POSITA would have been fully capable of modifying Aizawa to feature a light permeable protruding convex cover to obtain the benefits attributed to such a cover by Ohsaki. For example, a POSITA would have found it obvious to include a circular light-permeable convex cover based on the teachings of Ohsaki, and take reasonable steps to make sure that the combination of a circular protruding convex cover would function with the other features present in Aizawa so as to provide the benefits discussed above.

B. A POSITA would have recognized the benefits of Ohsaki's teachings when applied to Aizawa's sensor

24. Masimo contends that "Ohsaki indicates that its sensor's convex board ***only*** improves adhesion when used on the ***back*** (i.e., watch) side of the wrist," and that "Aizawa ***requires*** its sensor be positioned on the palm side of the wrist," and therefore reaches a conclusion that "[a] POSITA seeking to improve adhesion of Aizawa's sensor would not incorporate a feature that only improves adhesion at a different and unsuitable measurement location." POR, 32. But Ohsaki does not describe that its sensor can ***only*** be used at a backside of the wrist, and Aizawa never requires that its sensor be positioned on the palm side of the wrist. Instead, at most, these disclosures simply describe these arrangements with respect to a preferred embodiment. APPLE-1014, [0019].

25. Indeed, Ohsaki's specification and claim language reinforce that Ohsaki's description would not have been understood as limited to one side of the wrist. For example, Ohsaki explains that "the detecting element 2…may be worn on the back side of the user's forearm" as one form of modification. *See* APPLE-1014, [0030], [0028] (providing a section titled "[m]odifications"). The gap between the ulna and radius bones at the forearm is even greater than the gap between bones at the wrist, which is already wide enough to easily accommodate a range of sensor sizes and shapes, including circular shapes. In addition, Ohsaki's claim 1 states that "the detecting element is constructed to be worn on a back side of a user's wrist ***or a user's forearm***." *See also* APPLE-1014, claims 1-2. As another example, Ohsaki's independent claim 5 and dependent claim 6 state that "the detecting element is constructed to be worn on a user's wrist or a user's forearm," ***without even mentioning a backside*** of the wrist or forearm. *See also* APPLE-1014,

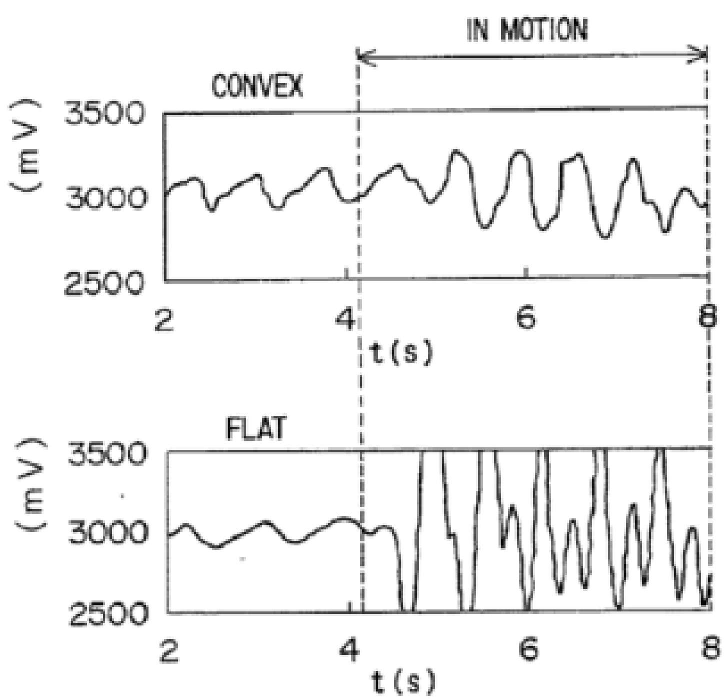
Claims 6-8. A POSITA would have understood this language to directly contradict Masimo's assertion that "[t]o obtain any benefit from Ohsaki's board, the sensor must be positioned on the backhand side of the wrist." POR, 22-23. A POSITA would have understood that Ohsaki's benefits provide improvements when the sensor is placed on either side of the user's wrist or forearm. APPLE-1014, [0025], FIGS. 4A, 4B. And while Masimo contends that Ohsaki teaches that a convex cover at the front (palm) side of the wrist somehow *increases* the tendency to slip, this is an argument that is nowhere supported by Ohsaki. *See* POR, 43. For instance, paragraph 23 and FIGS. 3A-3B of Ohsaki that Masimo points to as allegedly providing support for this incorrect argument mentions nothing about the flat/convex nature of the cover and is instead merely demonstrating that pulse detection is generally less reliable when the user is in motion (and thus would benefit from changes such as adding a convex cover). APPLE-1014, [0024], FIGS. 4A, 4B.

26. POR presents several arguments with respect to Ground 1 that are premised on Ohsaki ***requiring*** the detecting element to be worn on a back side of a user's wrist or a user's forearm. Because Ohsaki requires no such location for the translucent board 8, these arguments fail.

27. Moreover, even assuming, for the sake of argument, that a POSITA would have understood Aizawa's sensor as being limited to placement on the backside of the wrist, and would have understood Ohsaki's sensor's "tendency to slip" when arranged on the front side as informing consideration of Ohsaki's teachings with respect to Aizawa, that ***would have further motivated*** the POSITA to implement a light permeable convex cover in

Aizawa's sensor, to improve detection efficiency of that sensor when placed on the palm side. APPLE-1014, [0015], [0017], [0023], [0025], FIGS. 1, 2, 3A, 3B, 4A, 4B.

28. When describing advantages associated with its translucent board, Ohsaki explains with reference to FIGS. 4A and 4B (reproduced below) that "if the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist," but that if the board "has a convex surface…variation of the amount of the reflected light…that reaches the light receiving element 7 is suppressed." APPLE-1003, ¶¶79-80; APPLE-1014, [0015], [0017], [0025].



APPLE-1014, FIGS. 4A, 4B

29. Contrary to Masimo's contentions, a POSITA would not have understood these benefits of a convex surface over a flat surface to be limited to one side or the other of the user's wrist, or to any particular location. APPLE-1014, [0023]-[0025]. Rather, a POSITA would have understood that, by promoting "intimate contact with the surface of the user's

skin," a light permeable convex cover would have increased adhesion and reduced slippage of Aizawa's sensor when placed on either side of a user's wrist or forearm, and additionally would have provided associated improvements in signal quality. APPLE-1014, [0015], [0017], [0025]; FIGS. 1, 2, 4A, 4B, claims 3-8; *see also* APPLE-1063, 87, 91. Indeed, a POSITA would have recognized that modifying Aizawa's flat plate to feature a convex protruding surface, as taught by Ohsaki, would have furthered Aizawa's stated goal of "improv[ing] adhesion between the sensor and the wrist" to "thereby further improve the detection efficiency." APPLE-1006, [0013], [0026], [0030], [0034].

30. Further, the POSITA would have been fully capable of employing inferences and creative steps when improving Aizawa based on Ohsaki's teachings, and would have expected success when applying those teachings. Indeed, a POSITA would have understood that adding a convex protrusion to Aizawa's flat plate would have provided an additional adhesive effect that would have reduced the tendency of that plate to slip. Among other things, it is well understood that physically extending into the tissue and displacing the tissue with a protrusion will provide an additional adhesive/gripping effect.

C. Modifying Aizawa's sensor to include a convex cover as taught by Ohsaki enhances the sensor's light-gathering ability

31. Masimo argues that the combined sensor "would direct light away from the detectors and thus decrease light collection and optical signal strength." *See, e.g.,* POR, 45-52. As explained below, a POSITA would have understood the opposite to be true—that a cover featuring a convex protrusion would improve Aizawa's signal-to-noise ratio by causing more light backscattered from tissue to strike Aizawa's photodetectors than would

have with a flat cover. APPLE-1063, 52, 86, 90; APPLE-1061, 84, 87-92, 135-141; APPLE-1017, 803-805; APPLE-1006, FIGS. 1(a)-1(b). The convex cover enhances the light-gathering ability of Aizawa's sensor.

32. Masimo and its witness, Dr. Madisetti, assert that "a POSITA would have believed that a convex surface would…direct[] light away from the periphery and towards the center of the sensor." In so doing, POR and Dr. Madisetti fail to articulate a coherent position—e.g., whether Masimo's position is that "all" light or only "some" light is directed "to" or "towards the center." POR, 23, 45-52, Ex. 2004, ¶¶52, 87-97.

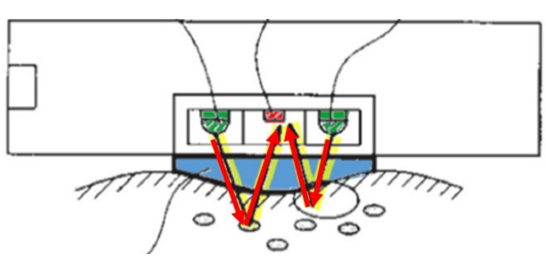
33. For example, Dr. Madisetti testified during deposition in one of the various related cases to this patent that "as I describe in my Declaration...if you have a convex surface...***all light*** reflected or otherwise would be condensed or directed towards the center." APPLE-1054, 40:4-11; *see also id.*, 127:22-128:18; Ex. 2004, ¶87 ("A POSITA Would Have Understood That a Convex Cover Directs Light ***To The Center*** Of The Sensor"). However, during the same deposition, Dr. Madisetti further stated that that a convex cover would redirect light "towards the center," which could be "a general area at which the convex surface would be redirecting…light" or "a point," while contrasting the phrase "to the center" from "towards the center." APPLE-1054, 105:12-107:1, 133:19-135:11.

34. In contrast, and as explained in more detail below, I have consistently testified that a POSITA would have understood that a convex cover improves "light concentration at pretty much ***all of the locations under the curvature of the lens***," and for at least that

reason would have been motivated to modify Aizawa's sensor to include a convex cover as taught by Ohsaki. Ex. 2006, 164:8-16.

i. Masimo ignores the well-known principle of reversibility

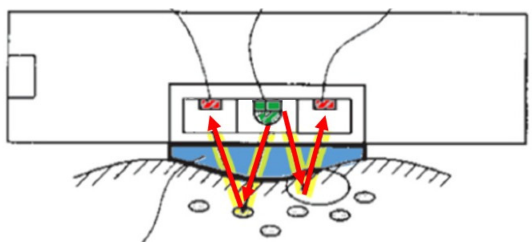
35. The well-known optical ***principle of reversibility*** dispels Masimo's claim that "a convex cover condenses light towards the center of the sensor and away from the periphery," when applied to Aizawa. POR, 45; APPLE-1061, 87-92; APPLE-1062, 106-111. According to the principle of reversibility, "a ray going from P to S will trace the same route as one from S to P." APPLE-1061, 92, 84; APPLE-1062, 101, 110; APPLE-1053, 80:20-82:20. Importantly, the principle dictates that rays that are not completely absorbed by user tissue will propagate in a reversible manner. In other words, every ray that completes a path through tissue from an LED to a detector would trace an identical path through that tissue in reverse, if the positions of the LED emitting the ray and the receiving detector were swapped. APPLE-1061, 92. To help explain, I have annotated Inokawa's FIG. 2 (presented below) to illustrate the principle of reversibility applied in the context of a reflective optical physiological monitor. As shown, Inokawa's FIG. 2, illustrates two example ray paths from surrounding LEDs (green) to a central detector (red):



APPLE-1008, FIG. 2 (annotated)

36. As a consequence of the principle of reversibility, a POSITA would have

understood that if the LED/detector configuration were swapped, as in Aizawa, the two example rays would travel identical paths in reverse, from a central LED (red) to surrounding detectors (green). A POSITA would have understood that, for these rays, any condensing/directing/focusing benefit achieved by Inokawa's cover (blue) under the original configuration would be identically achieved under the reversed configuration:



APPLE-1008, FIG. 2 (annotated)

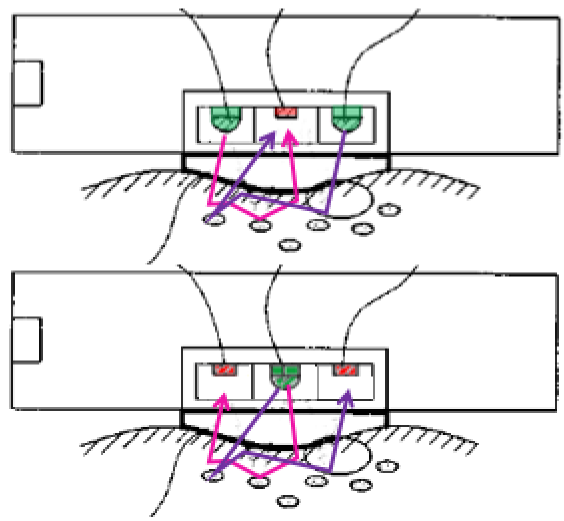
37. When factoring in additional scattering that may occur when light is reflected within human tissue, reversibility holds for each of the rays that are not completely absorbed; consequently, "if we're concerned with the impact of the lens on the system, it's absolutely reversible." APPLE-1059, 209:19-21, 207:9-209:21 ("one could look at any particular randomly scattered path…and the reversibility principle applies to all of the pieces [of that path] and, therefore, applies to the aggregate").

38. An example of reversibility in a situation with diffuse light, such as is present when LEDs illuminate tissue, is shown below from Hecht's Figure 4.12.

Figure 4.12 (a) Specular reflection. (b) Diffuse reflection. (Photos courtesy Donald Dunitz.)

39. In this figure 4.12a, collimated light is incident on a smooth surface, and exhibits specular reflection, in which parallel light rays encounter and are reflected from the surface and remain parallel. A POSITA would certainly understand specular reflection. In the case of the reflection as shown in Figure 4.12b, the random roughness of the surface scatters the incoming rays into many directions, and the resulting light would appear to be diffuse. However, even in this circumstance, the principle of reversibility applies–each individual ray can be reversed such that a ray travelling to the surface and scattered in a random direction can be followed backwards along exactly the same path.

40. In more detail, and as shown with respect to the example paths illustrated below (which include scattering within tissue), each of the countless photons travelling through the system must abide by Fermat's principle. APPLE-1062, 106-111. Consequently, even when accounting for various random redirections and partial absorptions, each photon traveling between a detector and an LED would take the quickest (and identical) path along the segments between each scattering event, even if the positions of the detector and LED were swapped.



41. To better understand the effect of a convex lens on the propagation of light rays towards or away from the different LEDs or detectors, the first and last segment of the light path may be representative of the light propagation of the various light rays. In the figures above, starting at the upper left, there is a pink-colored light ray emerging from the green LED and passing through the convex lens and entering the tissue. On the lower left, there is a pink-colored light ray leaving the tissue and entering the convex lens. As drawn, these rays are the same in position and orientation, except that the direction is exactly reversed. This illustration is consistent with the Principle of Reversibility as applied to this pair of possible light rays. According to the principle of reversibility, the upper light path from the LED to the first interaction with a corpuscle is exactly reversed. This same behavioral pattern applies to all of the segments of the many light paths that cross the interface at the surface of the convex lens. Importantly, in this example, the convex lens does not refract the incoming ray in a different direction from the outgoing ray, e.g., in a direction towards the center different from the outgoing ray. As required by the principle of reversibility, this incoming ray follows the same path as the outgoing ray, except in the reverse direction.

This statement is true for every segment of these light paths that crosses the interface between the tissue and the convex lens. Any ray of light that successfully traverses a path from the LED to the detector, that path already accounts for the random scattering as that scattering is what allowed the ray to go from the LED to a detector along the path to thereby be subsequently detected by the detector. A POSITA would have understood that the path is an aggregation of multiple segments and that the path is reversible as each of its segments would be reversible, consistent with Fermat's principle.

42. The statement about the reversibility of the segments of the light path which cross the interface between tissue and convex lens is consistent with the well-known and well-established Snell's law, which provides a simple algebraic relation between the angles of incidence and refraction as determined by the two indices of refraction. And Snell's law supports the basic understanding that the path of the light rays to/from a scattering event across the interface to/from the convex lens and on to/from the LED or photodetector must be reversible.

43. Based on this understanding of light rays and Snell's law, a POSITA would have understood that the positions of the emitters and detectors can be swapped in the proposed combination, and that the light paths from the initial situation would be reversed in the altered situation.

44. When confronted with this basic principle of reversibility during deposition, Dr. Madisetti refused to acknowledge it, even going so far as to express ignorance of "Fermat's principle, ***whatever that is***." APPLE-1054, 89:12-19. Yet Fermat's principle, which states

that a path taken by a light ray between two points is one that can be traveled in the least time, regardless of the direction of travel, is one of the most fundamental concepts in optics/physics and plainly requires the basic principle of reversibility. APPLE-1061, 87-92; APPLE-1062, 106-111. This is in no way a new theory, as this core concept dates back many years, and is offered in Aizawa itself. Indeed, ***Aizawa recognizes this reversibility***, stating that while the configurations depicted include a central emitter surrounded by detectors, the "same effect can be obtained when…a plurality of light emitting diodes 21 are disposed around the photodetector 22." APPLE-1006, [0033]; APPLE-1059, 209:19-21.

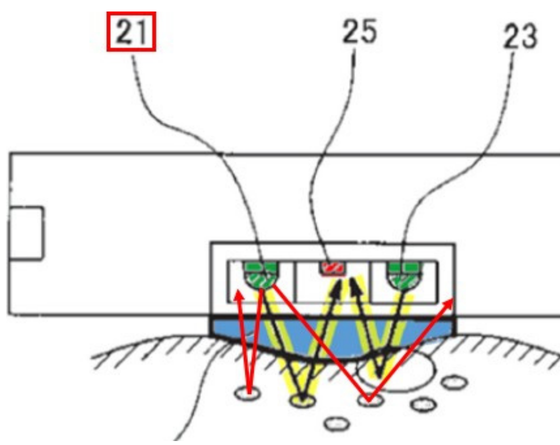
45. In short, based at least on the principle of reversibility, a POSITA would have understood that both configurations of LEDs and detectors—*i.e.*, with the LED at the center as in Aizawa or with the detector at the center as in Inokawa—would identically benefit from the enhanced light-gathering ability of a convex lens/protrusion.

ii. Masimo ignores the behavior of scattered light in a reflectance-type pulse sensor

46. Because Aizawa is a reflectance-type pulse sensor that receives diffuse, backscattered light from the measurement site, its cover/lens cannot focus all incoming light toward the sensor's center. Ex. 2006, 163:12-164:2 ("A lens in general…doesn't produce a single focal point"). Indeed, reflectance-type sensors work by detecting light that has been "partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector." APPLE-1063, 86. A POSITA would have understood that light which backscatters from the measurement site after diffusing

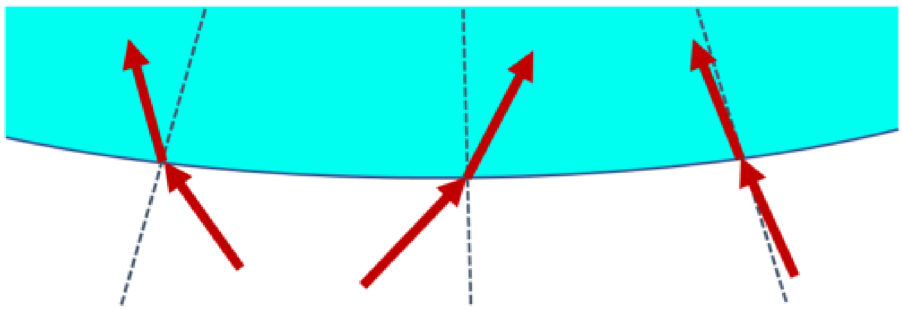
through tissue reaches the active detection area from various random directions and angles. APPLE-1056, 803; APPLE-1063, 90, 52.

47. As noted above, basic law of refraction, namely Snell's law, dictates this behavior of light. APPLE-1061, 84; APPLE-1062, 101; APPLE-1053, 80:20-82:20; APPLE-1063, 52, 86, 90. For example, referring to Masimo's version of Inokawa's FIG. 2, further annotated below to show additional rays of light emitted from LED 21, it is clearly seen how some of the reflected/scattered light from the measurement site does not reach Inokawa's centrally located detector:



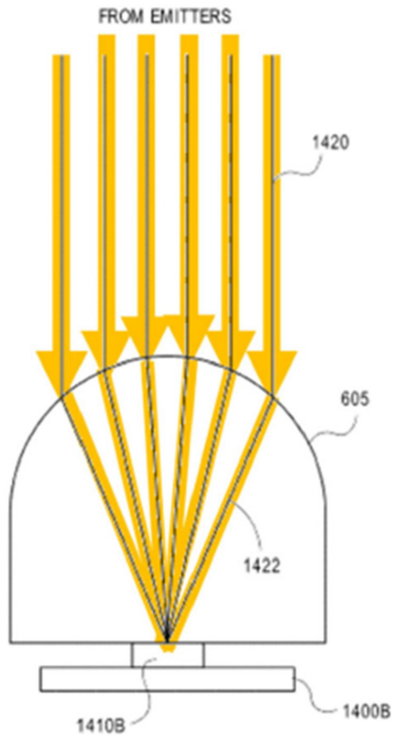
APPLE-1008, FIG. 2 (annotated); POR, 15.

48. For these and countless other rays that are not shown, there is simply no way for a cover to focus all light at the center of the sensor device. APPLE-1061, 84; APPLE-1062, 101; APPLE-1053, 80:20-82:20. The illustration I provide below shows how Snell's law determines a direction of a backscattered ray within a convex cover, thus providing a stark contrast to Masimo's assertions that all such rays must be redirected to or towards the center:



49. Indeed, far from focusing light to the center as Masimo contends, Ohsaki's convex cover provides a slight refracting effect, such that light rays that may have otherwise missed the detection area are instead directed toward that area as they pass through the interface provided by the cover. This is particularly true in configurations like Aizawa's in which light detectors are arranged symmetrically about a central light source, so as to enable backscattered light to be detected within a circular active detection area surrounding that source. APPLE-1063, 86, 90. The slight refracting effect is a consequence of the similar indices of refraction between human tissue and a typical cover material (e.g., acrylic). APPLE-1057, 1486; APPLE-1058, 1484).

50. To support the misguided notion that a convex cover focuses all incoming light at the center, Masimo relies heavily on the '195 patent's FIG. 14B (reproduced below):



APPLE-1001, FIG. 14B (as annotated at POR, 47)

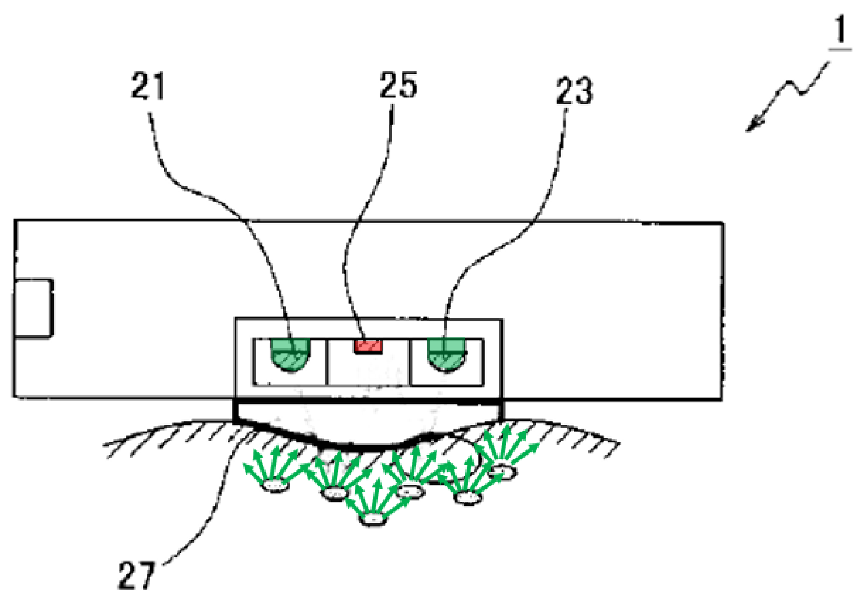
51. Masimo and Dr. Madisetti treat this figure as an illustration of the behavior of all convex surfaces with respect to all types of light, and conclude that "a convex surface condenses light away from the periphery and towards the sensor's center." POR, 46-47; APPLE-1054 ("…a POSA viewing [FIG. 14B]…would understand that light, ***all light***, light from the measurement site is being focused towards the center").

52. But the incoming collimated light shown in FIG. 14B is not an accurate representation of light that has been reflected from a tissue measurement site. The light rays (1420) shown in FIG. 14B are collimated (i.e., travelling paths parallel to one another), and each light ray's path is perpendicular to the detecting surface.

53. By contrast, the detector(s) of reflectance type pulse detectors detect light that has been "partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector." APPLE-1063, 86. For example, a POSITA would have understood from Aizawa's FIG. 1(a) that light that backscatters from the measurement site after diffusing through tissue reaches the circular active detection area provided by Aizawa's detectors from various random directions and angles, as opposed to all light entering from the same direction and at the same angle as shown above in FIG. 14B. APPLE-1063, 52, 86, 90; APPLE-1017, 803-805; *see also* APPLE-1012, FIG. 7. Even for the collimated light shown in FIG. 14B, the focusing of light at the center only occurs if the light beam also happens to be perfectly aligned with the axis of symmetry of the lens. If for example, collimated light were to enter the FIG. 14B lens at any other angle, the light would focus at a different location in the focal plane. Further, if the light were not collimated, so that rays enter the lens with a very wide range of incident angles, there would be no focus at all, and many rays will be deflected away from the center. Moreover, since "the center" takes up a very small portion of the total area under the lens, the majority of rays associated with diffuse light entering the lens would arrive at locations away from the center.

54. The light rays from a diffuse light source, such as the LED-illuminated tissue near a pulse wave sensor or a pulse oximeter, include a very wide range of angles and directions, and cannot be focused to a single point/area with optical

elements such as lenses and more general convex surfaces. The example figure below illustrates light rays backscattered by tissue toward a convex lens; as consequence of this backscattering, a POSITA would have understood that the backscattered light will encounter the interface provided by the convex board/lens at all locations from a wide range of angles. This pattern of incoming light cannot be focused by a convex lens towards any single location.



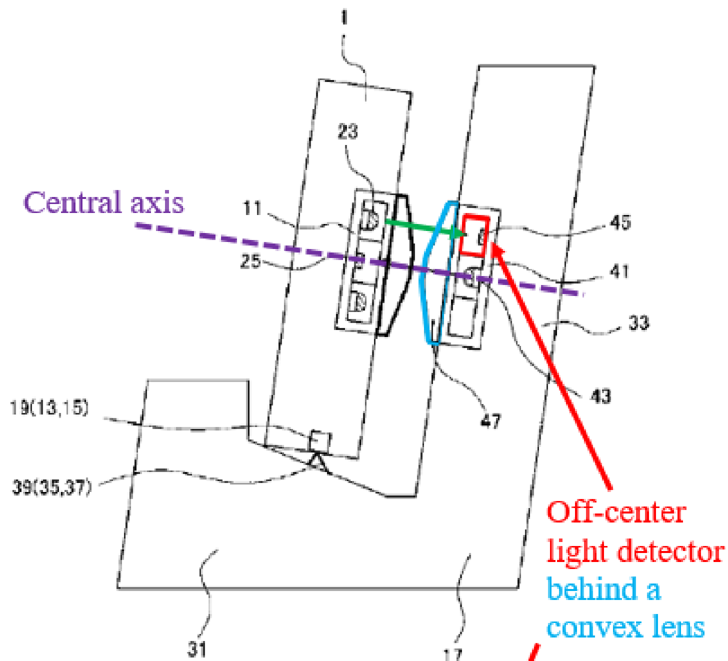
APPLE-1061, 141 (annotated)

55. To the extent Masimo contends that only *some* light is directed "towards the center" and away from Aizawa's detectors in a way that discourages combination, such arguments also fail. Indeed, far from *focusing* light to a single central point, a POSITA would have understood that Ohsaki's cover provides a slight refracting effect, such that light rays that may have missed the active detection area are instead directed toward that area as they pass through the interface provided by the lens. APPLE-1063, 52; APPLE-1007, [0015]; APPLE-

1061, 87-92, 135-141; APPLE-1054, 60:7-61:6, 70:8-18.

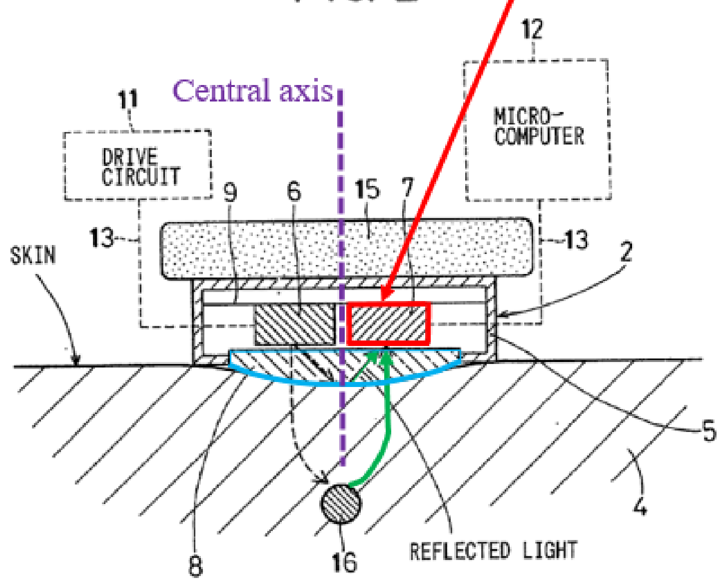
56. Masimo's technically and factually flawed argument is exposed by multiple prior art references, including the Ohsaki and Inokawa references which are the key elements of our combinations. As shown in the figures below, Ohsaki and Inokawa both show embodiments which use a convex lens to direct light to detectors that are not located at the center of a sensor. APPLE-1014, FIG. 2; APPLE-1008, FIG. 3. In Inokawa's Figure 2, an off-center emitter and sensor are configured to send and receive text messages, and are capable of success, even though the detector is not positioned at the center.

(FIG. 3)



APPLE-1008, FIG. 3

FIG. 2

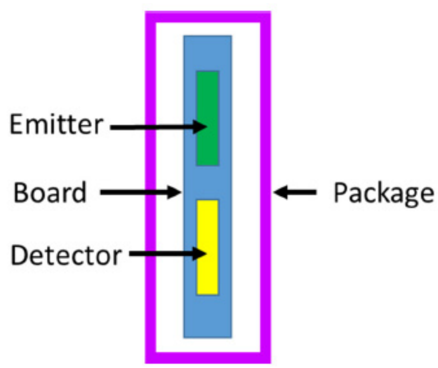


APPLE-1014, FIG. 2

57. If, as asserted by the Patent Owner, a convex lens is required to condense, direct, or focus the light to the center, the embodiments disclosed by Ohsaki and Inokawa would all fail because there is no detector at the center to detect all of

the light that would be directed towards the center by the convex board. The Ohsaki and Inokawa embodiments (reproduced above) do not show or otherwise teach that its convex board directs all light towards the center.

58. Moreover, even in Patent Owner and Dr. Madisetti's illustration (shown below), which represents their understanding of Ohsaki's FIGS. 1 and 2, the detector is not located in the center. Ex. 2004, ¶38. If Patent Owner and Dr. Madisetti's arguments were correct (which they are not), Ohsaki embodiments in FIGS. 1 and 2 would fail to produce a functioning pulse wave sensor—which is not the case—and Patent Owner has never claimed the same either.



Ex. 2004, ¶38

59. For all of these reasons, including details from the interpretation of Ohsaki's embodiment provided by Dr., Madisetti and the Patent Owner, it would have been obvious to a POSITA that a convex cover would have been successfully used with a sensor design with peripheral detectors (as in Aizawa and Ohsaki), and that it would be reasonable to expect the benefits of improved adhesion as explained above and in my previous declaration.

D. A POSITA would have been motivated to select a convex cover to protect the optical elements

60. Masimo contends that "a POSITA would have understood that Aizawa's flat plate would provide better protection than a convex surface" and be "less prone to scratches." POR, 52-53. Even assuming this to be true, one possible disadvantage that competes with the known advantages of applying Ohsaki's teachings to Aizawa's sensor would not have negated a POSITA's motivation to combine. Moreover, a POSITA would have understood the ***multiple*** advantages of a convex cover described in my earlier declaration outweigh any alleged possibility of scratching (which, at any rate, has nothing whatsoever to do with the protection of optical elements within Aizawa's sensor). Moreover, by choosing a suitable material of the protrusion to be scratch-resistant, such as glass, it would have been obvious for a POSITA to achieve both benefits (light gathering and scratch-resistance) at once.

E. Patent Owner mischaracterizes Aizawa's principle of operation

61. Masimo appears to be arguing that Aizawa's photodetectors cannot be connected in parallel because Aizawa seeks to "help address sensor dislocation" and that this function, for some reason, cannot be maintained if its detectors were connected in parallel. POR, 54-57. As I explain in more detail below, this argument from Patent Owner either completely misunderstands and/or mischaracterizes Aizawa's actual teachings.

62. As I mentioned during my deposition, a POSITA would have recognized

and/or found it obvious that the photodetectors of Aizawa are connected in parallel. Ex. 2026, 72:3-9. This is because a POSITA would have known that connecting multiple photodetectors together in parallel allows the current generated by the multiple photodetectors to be added to one another, which would subsequently ensure that even if one of multiple sensors connected in parallel were to be displaced so as to receive no signal, the fact that all the sensors are connected in parallel such that their signals are summed means that a signal will still be detected, in accordance with Aizawa's objective. As explained by Aizawa, the pulse rate is determined by computing the number of outputs above the threshold value per unit time (Aizawa paragraph 28), which is consistent with how a POSITA would consider analyzing the output based on summing of the sensor currents. I explained this previously in my first declaration. APPLE-1003, ¶¶105-106. Thus, to the extent Aizawa itself doesn't expressly teach connecting its photodetectors in parallel, this is merely an implementation detail that a POSITA would have been well aware of (and in fact performed very commonly). *See* APPLE-1024, 3017; APPLE-1025, 4:23-30. Patent Owner seems to be of the view that FIG. 3 of Aizawa somehow supports their false assertion that Aizawa's sensors cannot be connected in parallel; however, FIG. 3 is merely a "schematic diagram" that is provided to illustrate what a waveform looks like. Indeed, there is no disclosure anywhere in Aizawa to suggest that it is even capable of somehow monitoring the signals of each photodetector, and there is certainly no

need to do so if its sensors are connected in parallel. APPLE-1006, [0019], [0028], FIG. 1(b). Instead of attributing the ability to account for sensor displacement to individually connected/monitored photodetectors, as Masimo appears to contend, Aizawa actually explains that the ability to account for sensor displacement comes from, among other things, disposing its photodetectors "around the light emitting diode and not linearly" and by "expand[ing]...the light receiving area." APPLE-1006, [0009], [0012]. Not surprisingly, these are precisely some of the benefits provided by the Aizawa combination as set forth.

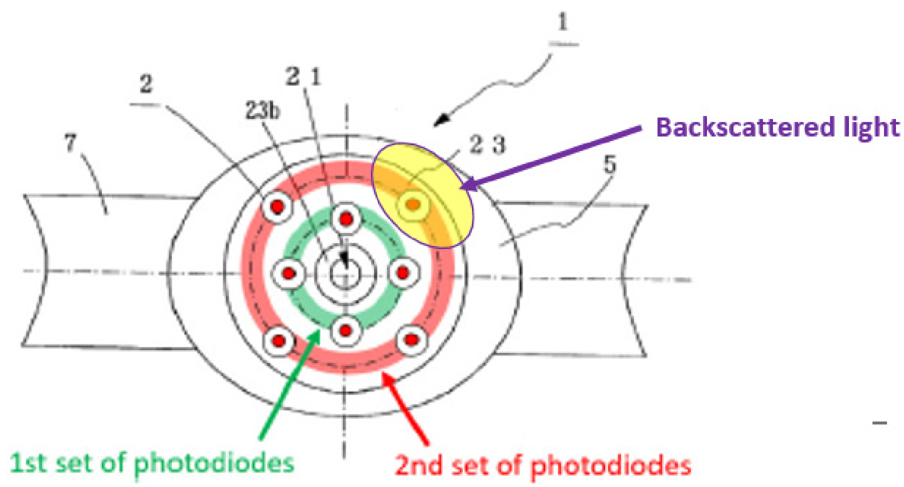
63. Thus, connecting Aizawa's photodetectors in parallel allows Aizawa to account for sensor displacement, instead of preventing it as Masimo alleges, since the signals from all the detectors will be included in the output, thereby allowing the system to account for any one detector that may not be receiving a signal due to displacement.

F. A POSITA would have been motivated to add a second ring of sensors to Aizawa

64. I previously explained at length why a POSITA would have been motivated to add a second ring of sensors to Aizawa, most notably to allow the modified system to "collect a bigger portion of backscattered light intensity." APPLE-1003, ¶¶ 57, 71, 76, 110-112. Yet inexplicably, Masimo argues that "Petitioner gives no plausible reason why a POSITA would have been motivated to modify Aizawa to add an entire second ring of four detectors farther from the emitter...." POR, 58; *see also* POR, 60 ("Petitioner never explains why, given

these straightforward options to increase signal strength, a POSITA would instead add an entire new circle of detectors farther from the emitter....").

65. But as I previously explained, adding a second ring of sensors to Aizawa allows the modified Aizawa system to "widen[] the active area of the PD" and consequently "collect a bigger portion of backscattered light intensity." APPLE-1003, ¶¶57-71; APPLE-1024, 3019. To illustrate, as shown below, a measurement scenario where the backscattered light only reaches the area highlighted in yellow would not result in light detection without the presence of additional sensors provided by the second ring:



APPLE-1006, FIG. 1(a)

66. Like I said during my deposition, "having a larger detector area is beneficial" because this would "fill up more of the space, that would give you the opportunity to capture more light reflected back from the tissue." Ex. 2026, 102:5-104:4.

67. Additionally, contrary to Masimo's arguments, adding a second ring of

detectors would not have led to an undesirable increase in power consumption. POR, 57-60. Among other things, the LEDs, not the photodetectors, are responsible for consuming the dominant power in the system. Ex. 2026, 104:5-105:14. Thus, widening the detection area to collect a bigger portion of backscattered light, as would be the case with the modified Aizawa system with two rings of detectors, would result in improved light collection efficiency by allowing additional light to be captured and thereby allowing a lower brightness of LEDs to be used, which would result in reduced power consumption. APPLE-1003, ¶¶70-71.

68. Even assuming for the sake of argument that power consumption is increased through this modification, which for reasons I explained above it would not, a POSITA nevertheless would have been capable of weighing potential tradeoffs, for instance increased power consumption vs. collection of more of the backscattered light than would be possible if detector placement was limited to only one ring. Such design choices are routinely made by a POSITA in consideration of the overall design/engineering objectives.

G. A POSITA would have been motivated to keep the first and second rings of detectors separate

69. Not able to dismiss the clear benefits that Mendelson-2003's two-ring design would provide to Aizawa, Masimo further tries to dismiss such teachings as being for "performing experiments." POR, 60. Masimo argues that "even if a POSITA would have added a second ring of detectors, Mendelson 2003

evidences that a POSITA would not have kept the first and second ring of detectors separate or separately amplified the aggregated signals." POR, 64. They appear to be arguing that Mendelson-2003 requires a single large photodetector that covers the same area covered by the two rings of detectors.

70. But Mendelson-2003 does not say that using a single, large detector is somehow superior to using multiple, smaller detectors. Instead, the main premise behind Mendelson-2003 is that the two situations are equivalent; that is why they are able to use one configuration (*e.g.,* two rings of detectors) in place of the other (*e.g.,* single large detector). Thus, a POSITA, looking to implement the teachings of Mendelson-2003 regarding the benefits of expanding the detection area, would have recognized that one way to achieve the same would be through the precise configuration as taught by Mendelson-2003, namely using two rings of discrete photodetectors that are each connected in parallel and that each provide a separate stream. Indeed, it is well known that a single larger photodetector can be replaced with multiple smaller ones. *See, e.g.,* APPLE-1016, 915 ("[W]e showed that a concentric array of ***either discrete PDs, or an annularly-shaped PD ring***, could be used to increase the amount of backscattered light detected..."). Thus, a POSITA trying to maximize the detection area to increase sensitivity and lower power consumption, as in Mendelson-2003, would have recognized that one way to implement this configuration is to, like Mendelson-2003, use two rings of parallel detectors.

71. Lastly, as I previously described in my first declaration, keeping the two signal streams separate provides multiple other benefits, such as detecting sensor displacement as well as being able to more reliably detect weak signals that are only picked up by the outer ring, for example, by utilizing different gain in the amplification of signals captured by the outer ring. *See* APPLE-1003, ¶¶107-109. Masimo's arguments that the benefits of maintaining separate streams as per Mendelson '799 in order to detect dislocation is inapplicable to the modified Aizawa system is misplaced because a POSITA would have recognized that Mendelson '799's general teachings regarding the comparison of "near" and "far" detectors in order to sense dislocation is more broadly applicable to the "near" and "far" rings in Aizawa-Mendelson-2003. APPLE-1025, 12:62-13:5, 13:19-30; APPLE-1003, ¶107. Moreover, Masimo's arguments that "the weaker signals at the outer ring are precisely why a POSITA would have used Aizawa's existing single ring embodiment" entirely misses the point that expanding the detection area by use of additional rings gives the system an opportunity to pick up weaker signals that otherwise would have been missed completely. POR, 64.

H. The claimed protrusion height in claims 9 and 15 would have been obvious to a POSITA

72. The POR argues that nothing in the references teaches or suggests that a protrusion with the claimed height in claims 9 and 15 would have been obvious, and dismisses the prior art mapping for claims 9 and 15 as hindsight based. POR, 66-69. As explained below, the POR ignores evidence establishing the

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.

Petitioner,

v.

MASIMO CORPORATION,

Patent Owner.

Case IPR2020-01733
U.S. Patent 10,702,195

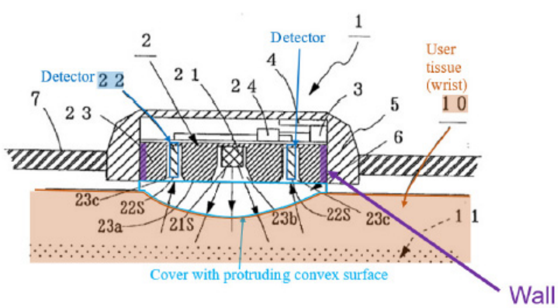
DECLARATION OF VIJAY K. MADISETTI, PH.D.

Masimo Ex. 2004
Apple v. Masimo
IPR2020-01733

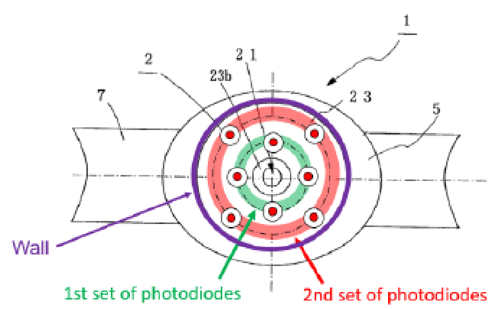
1. A POSITA Would Have Understood That Ohsaki's Rectangular Board Would Not Work With Aizawa's Circular Sensor Arrangement

a) Modifying Ohsaki's Rectangular Board Would Eliminate The Limited Advantage Of Reduced Slipping Taught By Ohsaki

53. Dr. Kenny's combination changes Ohsaki's structure and eliminates the longitudinal shape that gives Ohsaki's rectangular board the ability to fit within the user's anatomy and prevent slipping. Ex. 1003 ¶80; Ex. 1014 ¶[0019]. Dr. Kenny's illustrated combination changes Ohsaki's rectangular board (discussed in Sections VII.A.1-2, above) and makes it circular so that it can cover Aizawa's holder 23 (which Dr. Kenny outlined in purple in the figure below):



Dr. Kenny's illustration of the combination of Ohsaki, Aizawa, Mendelson 2003, and Goldsmith (Ex. 1003 ¶114)

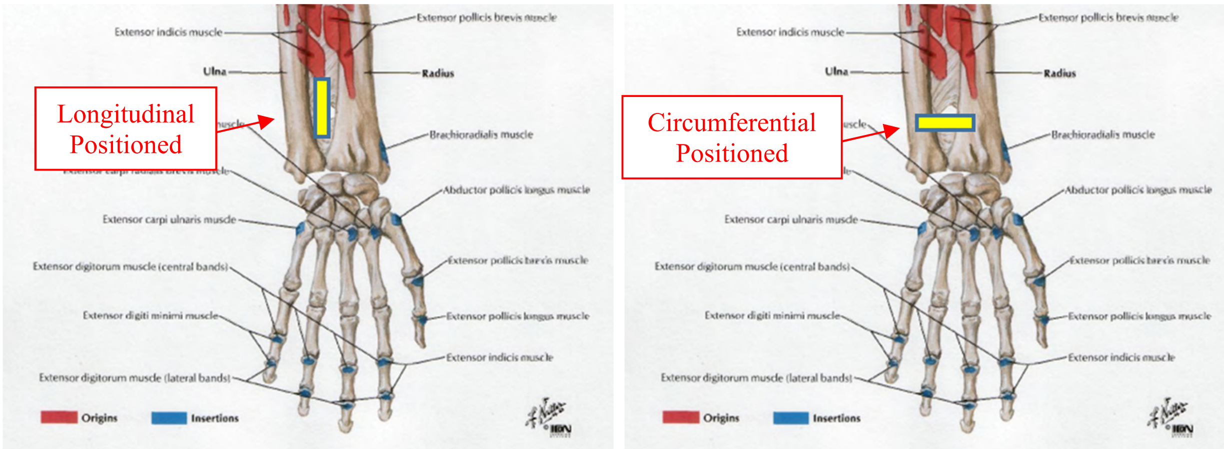


Dr. Kenny's illustration of Aizawa's modified circular sensor (Ex. 1003 ¶111)

54. Dr. Kenny asserts that a POSITA would have been motivated to add Ohsaki's rectangular board to Aizawa's circular sensor to improve adhesion. Ex. 1003 ¶80; *see also, e.g.*, ¶¶77, 81. As an initial point, Ohsaki does not specifically discuss improving adhesion, and instead refers to a particular configuration that

prevents slipping and various other configurations that have a tendency to slip. Ex. 1014 ¶¶[0006], [0010], [0019], [0023], [0025]. Dr. Kenny equates Ohaski's disclosure of a convex surface that prevents slippage with "improv[ing] adhesion." Ex. 1003 ¶80 (citing Ex. 1014 ¶[0025]). But Dr. Kenny's proposed modification eliminates the longitudinal shape that Ohsaki identifies as an important part of reducing slipping. Ex. 1014 ¶[0019].

55. Ohsaki places its linear, longitudinal sensor on the backhand side of a user's wrist to avoid interacting with bones in the wrist. *See* Ex. 1014 ¶¶[0006] (discussing need to avoid pressing on "two bones (the radius and the ulna)"), [0024] ("the radius and the ulna inside the user's wrist 4 are not pressed"); *see also*, *e.g.*, ¶¶[0023]-[0024], Abstract, Title, Fig. 1 (Ohsaki device worn on back side of wrist). As illustrated below (left), the forearm bones (the radius and ulna) on the arm's backhand (or watch) side create a longitudinal opening at the junction between the wrist and forearm with no muscle insertions. Ex. 2010 at 49 (Plate 434). The radius and ulna, against which Ohsaki warns against pressing (Ex. 1014 ¶¶[0006], [0024]), are on either side of this longitudinal opening.

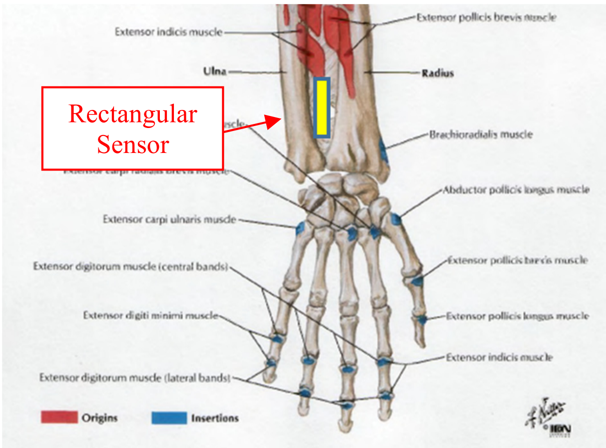


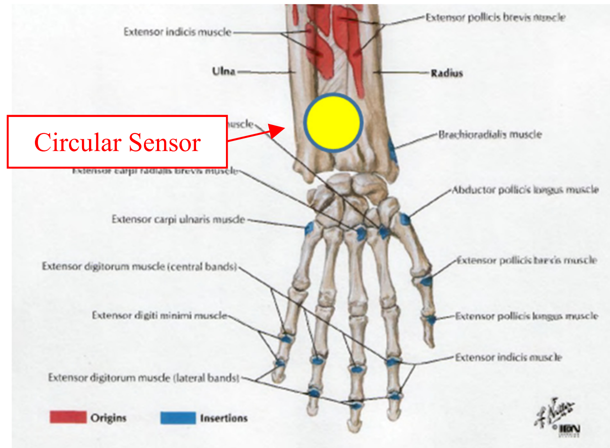
Anatomical drawing of the back side (posterior) of the hand, wrist, and forearm (partial view from Ex. 2010 at 49 (Plate 434))
Left: Conceptual view of how a rectangular sensor that is positioned in longitudinal direction on the wrist/forearm can avoid the radius and ulna
Right: Conceptual view of how the same rectangular sensor placed in the circumferential direction on wrist/forearm interacts with the radius and ulna

56. Ohsaki indicates that its sensor's longitudinal direction needs to be aligned with the longitudinal direction of the longitudinal opening of the user's arm to prevent slipping. Ex. 1014 ¶[0019]. If the sensor's longitudinal direction is aligned with the circumferential direction of the user's wrist, the undesirable result is "a tendency [for Ohsaki's sensor] to slip off." Ex. 1014 ¶[0019]. As illustrated above (right), a rectangular structure like Ohsaki's sensor and board that is aligned with the circumferential direction of the user's wrist undesirably interacts with the radius and ulna, which Osaki warns against. Ex. 1014 ¶¶[0006], [0024]. In contrast, a rectangular structure aligned with the longitudinal direction of the user's wrist can avoid pressing against the radius and ulna.

57. Thus, a POSITA would have understood that changing the shape of Ohsaki's rectangular board to circular would not preserve its ability to prevent slipping. Instead, if Ohsaki's rectangular board were changed into a circular shape, a POSITA would have believed it would have resulted in slipping, and thus eliminated the advantage of Ohsaki's board. This is because a circular shape extends equally in all directions, including in the circumferential direction of the user's wrist, which Ohsaki explains results in slipping. Ex. 1014 ¶[0019]. As a result, a circular shape cannot be placed in a longitudinal direction and thus cannot align with the longitudinal direction of the user's wrist, as taught by Ohsaki. As illustrated below, unlike a longitudinal sensor, a symmetrical circular shape (with a diameter equal to the long side of the rectangle, below left) would not fit within the user's anatomy in a way that it could avoid undesirably pressing against the user's radius and ulna, which Ohsaki cautioned against.

<u>Ohsaki's Longitudinal Teachings</u> <u>Dr. Kenny's Proposed Combination</u>





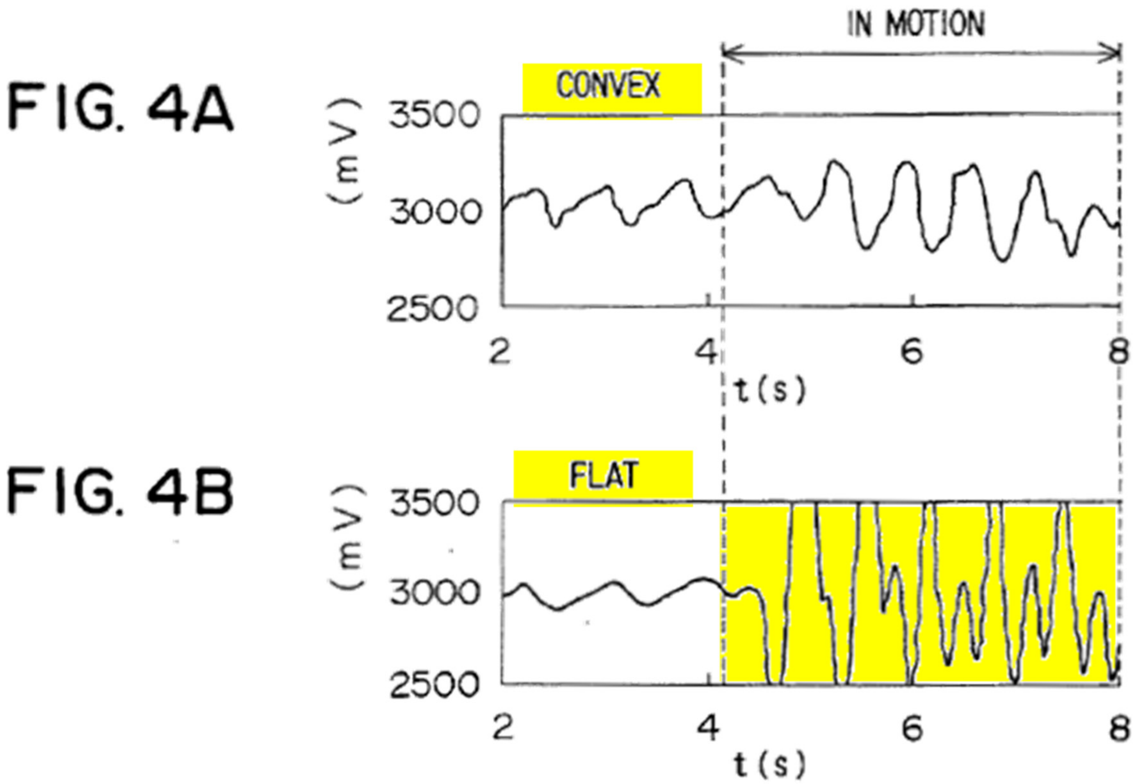
Anatomical drawing of the back side (posterior) of the hand, wrist, and forearm (partial view from Ex. 2010 at 49 (Plate 434))
Left: Conceptual view of how a rectangular sensor that is positioned in longitudinal direction on the wrist/forearm can avoid the radius and ulna
Right: Conceptual view of how a circular sensor with the same diameter as the length of the rectangular board interacts with the radius and ulna

58. Because a symmetrical circular shape will press on the user's arm in all directions, it will interact with the user's bone structure. Ohsaki teaches that such interactions with the user's anatomy are undesirable and result in slipping. Ex. 1014 ¶¶[0006], [0023]-[0024].

59. Dr. Kenny did not discuss Ohsaki's disclosure that when Ohsaki's rectangular sensor was placed in one orientation (up-and-down the arm), it helped prevent slipping. Ex. 1014 ¶[0019]. Dr. Kenny also did not discuss Ohsaki's explanation that rotating the sensor 90 degrees, such that the long direction points in the circumferential direction of the user's wrist, the sensor "has a tendency to slip." Ex. 1014 ¶[0019]; *see* Ex. 1003 ¶¶59-60, 77-85.

identified by Ohsaki corresponds to the irregular pattern shown in Figure 3B, compared to the pattern of measurements from the back side of the wrist shown in Figure 3A. For measurements using a convex board on the back side of the wrist, Ohsaki explains Figure 3A shows "the pulse wave is detected stably without being affected by the movement of the user's wrist...." Ex. 1014 ¶[0024].

79. Dr. Kenny does not cite or discuss Ohsaki's Figures 3A-3B when discussing the motivation for modifying Aizawa's palm-side sensor with a lens/protrusion similar to Ohsaki's board. Ex. 1003 ¶¶77-85; *see also* ¶¶114-117. Instead, Dr. Kenny discusses Ohsaki's Figures 4A-4B, which compares measurements using a sensor with a convex surface or a flat surface on the back (i.e., watch) side of the wrist. Ex. 1003 ¶¶78-79.



Ohsaki Figs. 4A-4B comparing convex and flat surfaces
for measurements taken from the back side of the wrist (color added)

80. Ohsaki states that Figure 4B shows that when measurements taken from the back side of the wrist using a sensor with a *flat* surface, "the detected pulse wave is adversely affected by the movement of the user's wrist." Ex. 1014 ¶[0025]. Ohsaki also indicates that a board with a *convex* surface prevents "slip[ping] off the detecting position" on the back side of the wrist, as shown in Figure 4A. Ex. 1014 ¶[0025]; *see also* ¶¶[0023]-[0024] (comparing tendency to slip on front and back side of wrist). Figure 4A, which illustrates Ohsaki's convex sensor placed on the back side of the wrist, contrasts with the measurements shown in Figure 3B (which illustrates a convex surface slips on the palm side of

the wrist). Figure 4A is consistent with Figure 3A (which illustrates a convex surface has comparatively less motion signal on the back side of the wrist). Taken together, A POSITA would have understood that Ohsaki's convex surface may prevent slipping on the back side of the wrist, if it is positioned appropriately (e.g., in the correct orientation with the long side up-and-down the wrist). Ex. 1014 ¶¶[0019], [0023]-[0025], Figs. 3A-3B, 4A-4B.

81. The rest of Ohsaki's disclosure recognizes the limitations on any benefit derived from its convex surface. Ohsaki repeatedly specifies that its sensor "is worn on the back side of a user's wrist corresponding to the back of the user's hand." Ex. 1014 Abstract; *see also* Title ("Wristwatch-Type Human Pulse Wave Sensor Attached On Back Side Of User's Wrist"), ¶[0008] (The "sensor according to the present invention…is worn on the back side of the user's wrist corresponding to the back of the user's hand."), ¶[0009] ("attached on the back side of the user's wrist by a dedicated belt"), ¶[0016] ("worn on the back side of the user's wrist"), ¶[0024] ("[T]he detecting element 2 is stably fixed to the detecting position of the user's wrist" when arranged on the back side of the user's wrist 4.). The only other possible location mentioned for placement of Ohsaki's sensor is "the back side of the user's forearm," which is adjacent to the wrist. Ex. 1014 ¶¶[0016], [0030]. Thus, in my opinion, for these reasons a POSITA would

not have been motivated to use Ohsaki's longitudinal board, which is designed to be worn on the back of a user's wrist, with Aizawa's palm-side sensor.

c) A POSITA Would Not Have Been Motivated To Eliminate The Identified Benefits Of Aizawa's Flat Adhesive Acrylic Plate By Including A Lens/Protrusion Similar To Ohsaki's Board

82. Dr. Kenny asserts that a POSITA would have been motivated to modify Aizawa's flat adhesive acrylic plate "to include a lens/protrusion (right), similar to Ohsaki's translucent board 8, so as to improve adhesion between the user's wrist and the sensor's surface, improve detection efficiency, and protect the elements within the sensor housing." Ex. 1003 ¶80. But a POSITA motivated to improve Aizawa's palm-side sensor would not have been motivated to add Ohsaki's convex board. As discussed above, Ohsaki teaches a POSITA that its convex board only provides advantages on the back side of the wrist, in a particular orientation. Ex. 1014 ¶¶[0019], [0025]. Ohsaki further teaches that on the palm side (front side) of the wrist, a sensor with a convex board, "has a tendency to slip off the detecting position of the user's wrist." Ex. 1014 ¶[0023], Figs. 3A-3B.

83. As discussed above, Aizawa teaches that a flat acrylic plate improves adhesion between the sensor and skin on the palm side of the wrist. *See* Sections VII.A.3, VII.B.2.a, above. Taken individually and together, both Ohsaki and Aizawa undermine Dr. Kenny's proposed addition of a convex lens/protrusion

similar to Ohsaki's translucent board to Aizawa's palm-side sensor to improve adhesion. Ex. 1003 ¶80. This is because, as explained above (Sections VII.B.2.a-b): (1) Aizawa teaches a *flat* acrylic plate *improves* adhesion on the wrist's *palm* side; (2) Ohsaki teaches a *convex* board "has a tendency to *slip*" on the wrist's *palm* side. As a result a POSITA reading Aizawa and Ohsaki would have affirmatively avoided modifying Aizawa's flat acrylic plate—which is taught to improve adhesion at Aizawa's sensor location on the palm side of the wrist—with a convex lens/protrusion similar to Ohsaki's convex board because Ohsaki's convex board is taught to slip on the palm side of the wrist where Aizawa's sensor is positioned. The table below summarizes these teachings.

	Front (Palm) Side	**Back Side**
Flat	Flat acrylic plate improves adhesion Ex. 1006 (Aizawa) ¶[0013]; *see also* ¶¶[0026], [0030], [0034], Fig. 1B **(Aizawa's sensor)**	Tends to slip Ex. 1014 (Ohsaki) ¶[0025], Figs. 4A-4B
Convex	Tends to slip Ex. 1014 (Ohsaki) ¶[0023], Figs. 3A-3B	Rectangular convex board prevents slipping Ex. 1014 (Ohsaki) ¶¶[0024]-[0025], Figs. 4A-4B **(Ohsaki's sensor)**

84. Dr. Kenny only considers Ohsaki's discussion of the impact of a convex versus flat surface on the back side of the wrist. *See, e.g.,* Ex. 1003 ¶¶77-85. But a POSITA would have understood that Ohskai's discussion regarding the

85. Based on Aizawa's teaching that a flat acrylic plate improves adhesion on the palm side of the wrist, and Ohsaki's teaching that a convex surface tends to slip on the palm side of the wrist, a POSITA would have come to the opposite conclusion from Dr. Kenny: that modifying Aizawa's "flat cover…to include a lens/protrusion…similar to Ohsaki's translucent board 8" would *not* "improve adhesion." *See, e.g.*, Ex. 1003 ¶80. As discussed above in this section, as well as Section VII.B.2, above, generally, Aizawa and Ohsaki, individually and together rebut Dr. Kenny's assertion that incorporating Ohsaki's convex surface is simply improving Aizawa's transparent plate 6 that has a flat surface "to improve adhesion between the user's wrist and the sensor's surface." Ex. 1003 ¶80. Thus, in my opinion, a POSITA would not have been motivated to modify Aizawa's flat acrylic plate, which improves adhesion at the measurement site on the palm side of the wrist, to include a convex lens/protrusion similar to Ohsaki's board, which tends to slip at the measurement site on the palm side of the wrist.

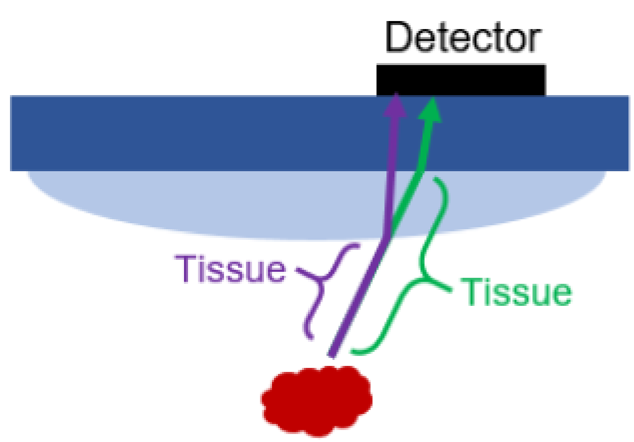
3. A POSITA Would Not Have Been Motivated To Reduce The Measured Optical Signal By Adding A Convex Lens/Protrusion To Aizawa's Sensor

86. Dr. Kenny's proposed combination is also problematic because Dr. Kenny detrimentally modifies Aizawa's flat cover to include a convex "lens/protrusion" positioned over peripheral detectors surrounding a centrally located emitter. Ex. 1003 ¶¶80, 114-117. As discussed below, a POSITA would

have understood that a convex "lens/protrusion" would direct light away from the detectors and thus result in decreased light collection and optical signal strength at the peripheral detectors — not increased signal strength as Dr. Kenny asserts. *See* Ex. 1003 ¶78 (arguing that the convex surface of the translucent board of Ohsaki "increases the strength of the signals").

a) A POSITA Would Have Understood That A Convex Cover Directs Light To The Center Of The Sensor

87. Petitioner and Dr. Kenny both admit that a convex cover condenses light passing through it towards the center of the sensor and away from the periphery. Petitioner and Dr. Kenny both illustrated this phenomenon in a petition filed against a related patent. In the Petition in IPR2020-01520 (Ex. 2019), Petitioner explained that a convex cover redirects light coming into the convex surface towards the center, as shown in Petitioner's figure below:



Petitioner's illustration from a related IPR showing that light hitting a convex surface is directed more centrally than light hitting a flat surface (Ex. 2019 at 45)

88. In his declaration in IPR2020-01520 (Ex. 2020), Dr. Kenny likewise confirmed that when using a convex surface, "the incoming light is 'condensed' toward the center." *See, e.g.,* Ex. 2020 at 69-70 (¶119); *see generally* Ex. 2020 69-71 (¶¶118-120), 115-117 (¶¶199-201). Dr. Kenny included the same illustration as Petitioner, which shows light passing through a convex surface is directed more towards the center, as compared to a flat surface. *See, e.g.*, Ex. 2020 at 69-71 (¶118-120).

89. The '195 Patent also confirms these admissions that a convex surface condenses light away from the periphery and towards the sensor's center. Figure 14B (below) "illustrates how light from emitters (not shown) can be focused by the protrusion 605 onto detectors." Ex. 1001 36:13-16. "When the light rays 1420 enter the protrusion 605, the protrusion 605 acts as a lens to refract the rays into rays 1422." Ex. 1001 36:23-25. As shown by Figure 14B of the '195 Patent, the convex shape directs light from the periphery toward the center. Ex. 1001 Fig. 14B.

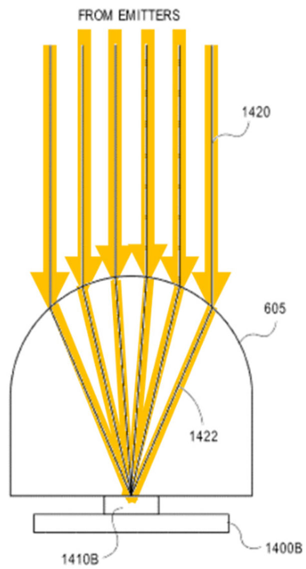


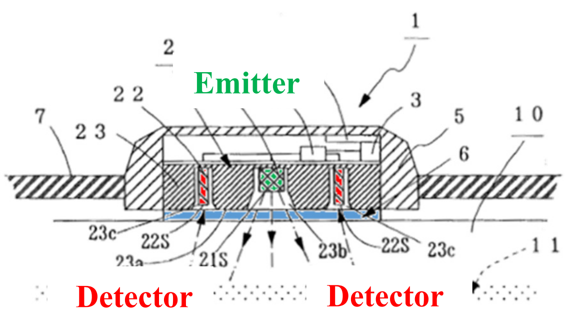
Illustration from the '195 Patent at issue, showing that light hitting a convex surface is directed towards the center
'195 Patent (Ex. 1001) Fig. 14B (highlighting added to show direction of light)

90. Accordingly, Petitioner, Dr. Kenny, and the '195 Patent all support that a POSITA would have understood that a convex lens/protrusion would direct incoming light towards the center of the sensor, as compared to a flat surface. In my opinion, a POSITA would have believed that light passing through a convex surface would have been directed to a more central location as compared to light passing through a flat surface. This would have been viewed as a detrimental result because, as discussed in the next section below, Aizawa's detectors are at the periphery of the sensor.

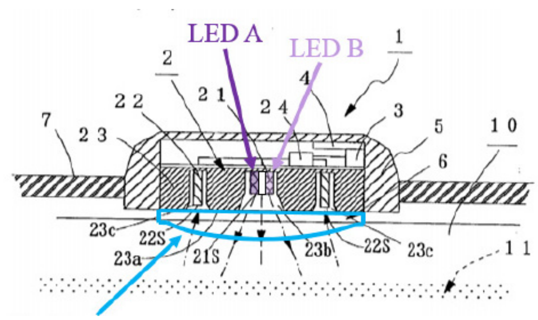
b) <u>A POSITA Would Not Have Been Motivated To Direct Light Away From Aizawa's Detectors</u>

91. Dr. Kenny asserts that a POSITA would have been motivated to modify Aizawa's flat adhesive acrylic plate with "a lens/protrusion" for improved

detection efficiency. Ex. 1003 ¶80. As illustrated below, Aizawa has peripherally located detectors (in red, below left) and a centrally located emitter (in green, below left) under a flat acrylic adhesive plate (in blue, below left). Ex. 1006 Fig. 1B; *see also, e.g.*, ¶¶[0009], [0026]-[0027], [0033], [0036]. Dr. Kenny's combination introduces a convex "lens/protrusion" (in blue, below right) over Aizawa's peripherally located detectors and centrally located light source (*see, e.g.*, Ex. 1003 ¶80):



Aizawa Fig. 1B (cross-section)
Red: detectors; Green: emitter,
Blue: flat plate

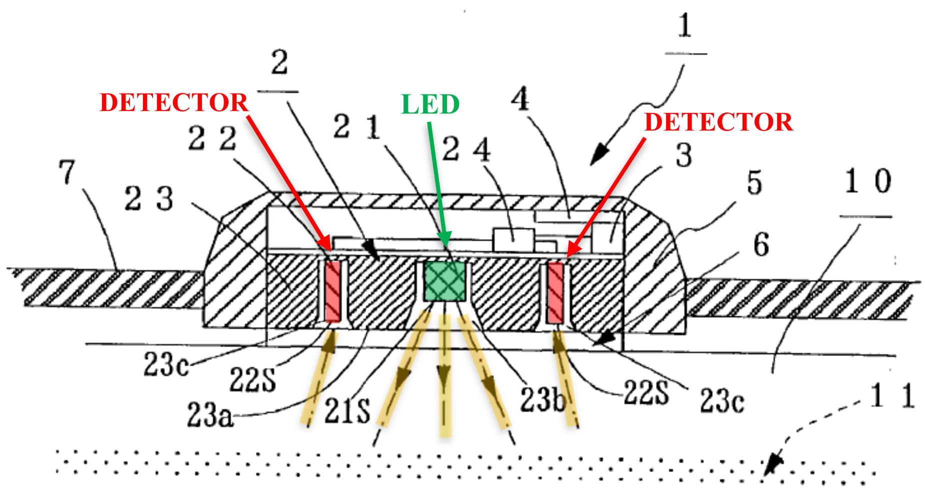


Dr. Kenny's proposed modifications
(Ex. 1003 ¶80)

Aizawa (Ex. 1006 Fig. 2) (color added) (left) versus
Dr. Kenny's proposed combination (Ex. 1003 ¶80) (right)

92. Dr. Kenny asserts that Ohsaki's board "increases the strength of the signals obtainable by Ohsaki's sensor." Ex. 1003 ¶78. However, as discussed above (Section VII.B.3.a), a POSITA would have believed that adding a convex lens/protrusion to Aizawa's flat adhesive acrylic plate would direct light away from the combination's detectors that are located on the periphery. Aizawa

illustrates that the light reaching Aizawa's detectors must travel from the center emitter to the outer periphery of the detectors. Ex. 1006 Fig. 1B, ¶[0027]. Aizawa shows the light path as leaving a single centrally located emitter, passing through the body, and reflecting back to periphery-located detectors (light must travel from the center emitter to the outer periphery to the detectors. Ex. 1006 Fig. 1B, ¶[0027]):

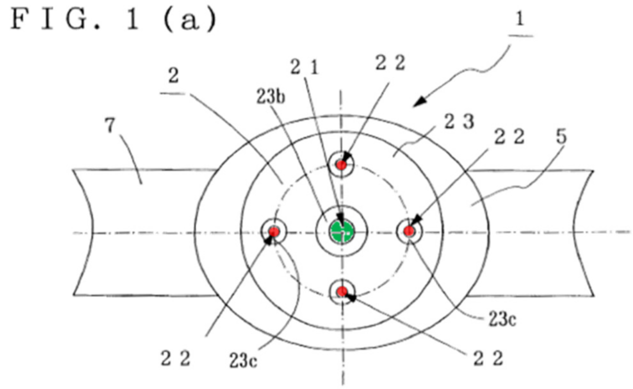


Aizawa Fig. 1B (cross-sectional view, color added)

93. Because of the configuration of Aizawa's sensor, with its central emitter and peripheral detectors, and the illustrated light path that requires light from the central emitter to reach the peripheral detectors, a POSITA would have understood that a change directing light to a more central location would decrease the optical signal at Aizawa's peripheral detectors. Ex. 1006 ¶¶[0026], [0030] (discussing benefits of Aizawa's flat "plate"). Because a POSITA would have believed that adding a convex lens/protrusion would have redirected light to a

more central location as compared to Aizawa's flat adhesive acrylic plate, a POSITA would have concluded that Dr. Kenny's proposed modification would decrease light-collection efficiency at Aizawa's peripheral detectors. Thus, I disagree with Dr. Kenny that a POSITA would have been motivated to modify Aizawa's flat plate to add a lens/protrusion similar to Ohsaki's translucent board based on the belief that it would have improved detection efficiency or otherwise increased signal strength. Ex. 1003 ¶80. As discussed above (Section VII.B.3.a) Dr. Kenny, the Petitioner, and the '195 Patent all support that a POSITA would have believed that adding a convex lens/protrusion would result in the light gathered and refracted to a more central location, and thus away from Aizawa's peripheral detectors, as compared to Aizawa's existing flat plate.

94. In addition, the addition of a convex lens/protrusion similar to Ohsaki's is particularly problematic because both Aizawa and Dr. Kenny's illustration of his combination include small detectors with small openings surrounded by a large amount of opaque material. Ex. 1006 Figs. 1A, 1B, 2; *see, also, e.g.*, Ex. 1003 ¶¶80, 95, 97, 98, 99, 101, 103, 111 (Dr. Kenny's illustrations). Aizawa's top-down view confirms the detectors' small size. Ex. 1006 Fig. 1A.



Aizawa's Features

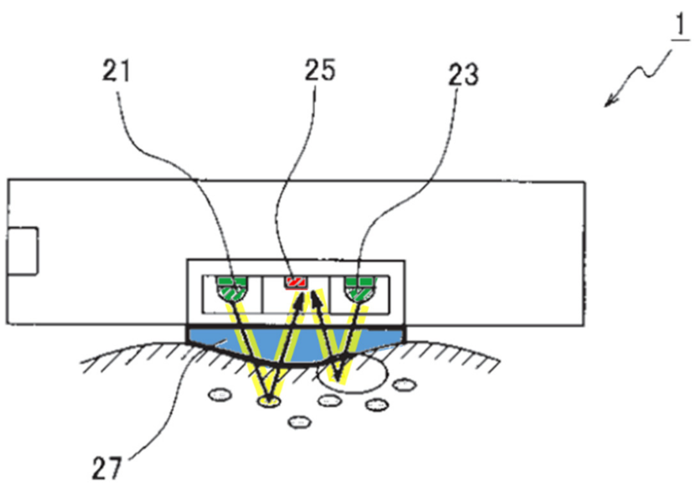
- **Green**: central emitter (21)
- **Red**: peripheral detectors (22)

Aizawa's sensor, showing small detectors (Ex. 1006 Fig. 1A, color added)

95. Thus, Dr. Kenny provides no evidence that a POSITA would have expected a convex lens/protrusion similar to Ohsaki's board to improve detection efficiency at Aizawa's peripheral detectors and increase signal strength. Ex. 1003 ¶¶78, 80. Instead, as explained above (Section VII.B.3.a), a POSITA would have expected that changing Aizawa's flat acrylic plate to a convex lens/protrusion similar to Ohsaki's board would reduce the amount of light gathered and refracted to Aizawa's peripheral detectors. The optical changes resulting from modifying Aizawa's flat surface to include a convex lens/protrusion similar to Ohsaki's board are thus another reason why a POSITA would not have been motivated to make that change.

96. Finally, Dr. Kenny relies on Inokawa for motivation to modify Aizawa's flat surface. Ex. 1003 ¶¶82-85. Dr. Kenny states that Inokawa would provide a "further rationale" (Ex. 1003 ¶82) to add the proposed a "lens/protrusion" (Ex. 1003 ¶80) to Aizawa. Dr. Kenny states that Inokawa

demonstrates "the additional benefit of increasing light collection efficiency, which would in turn lead to an improved signal-to-noise and more reliable pulse detection," based on "refracting/concentrating incoming light signals reflected by the blood." Ex. 1003 ¶83. Unlike Aizawa's circular ring of detectors around a central emitter, Inokawa's sensor is a linear sensor that uses a convex lens (27) to focus light from LEDs (21, 23) positioned on the periphery of the sensor to a single detector (25) in the center. Ex. 1008 ¶[0058], Fig. 2; *see also id.* ¶[0015] ("This lens makes it possible to increase the light-gathering ability of the LED as well as to protect the LED or PD.").



Inokawa's Features

- **Green**: peripheral emitters (21, 23)
- **Red**: central detector (25)
- **Blue**: convex lens (27)
- Arrows showing the direction of light in original, highlighting in yellow added

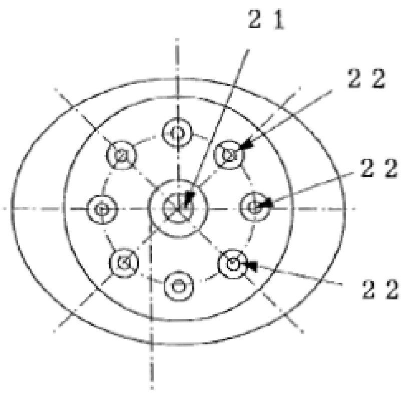
Inokawa Fig. 2 (color added)

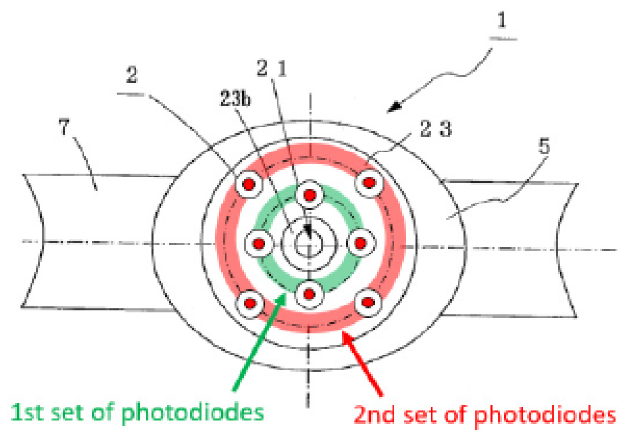
97. As illustrated above, Inokawa's linear detector-emitter configuration is different from Aizawa's circular detector arrangement. In Inokawa's sensor, light from Inokawa's periphery-located LEDs will reflect off the body and pass through the lens, which directs incoming light to the centrally located detector.

Ex. 1008 ¶[0058]. Inokawa's convex surface thus concentrates incoming light towards the sensor's center, where the detector is located, and away from the periphery. In contrast, Aizawa's detectors are not located at the center—they surround the central emitter. Inokawa would thus have further demonstrated to a POSITA that the proposed combination would decrease light gathering at Aizawa's peripheral detectors, which is the opposite of Dr. Kenny's motivation to combine. Ex. 1003 ¶83.

4. A POSITA Would Not Have Selected A Convex Cover To Protect The Sensor's Optical Elements

98. Dr. Kenny also asserts that a POSITA would have been motivated "to modify the [Aizawa] sensor's flat cover…to include a lens/protrusion…similar to Ohsaki's translucent board 8, so as to…protect the elements within the sensor housing." Ex. 1003 ¶80. As illustrated below, Aizawa already includes a flat adhesive acrylic plate (blue) that protects the elements (emitter, detectors) within the sensor housing. Ex. 1006 Fig. 1B; *see also, e.g.*, ¶¶[0023]-[0026], [0030]. Thus, in my opinion, a POSITA would not have been motivated to modify Aizawa's existing flat adhesive acrylic plate to add a convex lens/protrusion similar to Ohsaki's board for protection because a POSITA would have understood that Aizawa's flat cover already protects the sensor's components. Ex. 1006 Fig. 1B; *see also, e.g.*, ¶¶[0023]-[0026], [0030]. Dr. Kenny asserts that the convex lens/protrusion "protect[s] the elements within the sensor housing" (Ex.





Aizawa Fig. 4A Dr. Kenny's Proposed Combination (Ex. 1003 ¶74)

108. Dr. Kenny does not give a plausible reason why a POSITA would have been motivated to modify Aizawa's structure and add a second ring of four detectors that is farther from the emitter. Dr. Kenny's suggestion is contrary to Aizawa's illustrated embodiment, which demonstrates that eight detectors readily fit into the existing ring, and assumes adding a second ring of four detectors that is farther from the emitter would have some benefit. Ex. 1003 ¶¶73-76. But Mendelson 2003 adds a second ring of detectors farther away from the emitter because there is no room for more detectors in the existing ring. Ex. 1024 Fig. 1. The proposed new "outer" ring of detectors is not needed in Aizawa, and a POSITA would have understood that Dr. Kenny's new outer ring would have received substantially lower light intensity and required relatively greater power consumption to use than additional detectors added to the "inner" ring. *See* Ex. 1024 at 4 (stating optical signal "is inversely related to the separation distance between the PD and the LEDs" and outer ring detectors require LEDs

"significantly higher currents"). A POSITA would have believed the proposed modification would result in greater power consumption as compared to Aizawa's existing 8-detector structure, all placed on the inner ring closer to the detector. This is particularly true because Dr. Kenny also proposes adding a convex cover that would direct light away from the outer ring of periphery-located detectors. *See* Sections VII.B.1-3, above. A POSITA motivated to achieve improved power savings—Dr. Kenny's stated motivation for his modification (Ex. 1003 ¶73)—would not have added an outer ring of detectors to Aizawa, and instead would have added detectors to Aizawa's existing ring as disclosed in Aizawa's already disclosed 8-detector embodiment that positions all eight detectors in a single concentric circle.

109. Dr. Kenny's proposed modification thus changes Aizawa's structure in a way that Mendelson 2003 itself indicates would result in relatively worse power consumption (Ex. 1024 at 4) compared to Aizawa's existing configuration. In my opinion, a POSITA seeking to increase the number of detectors would have implemented Aizawa's existing eight detector arrangement, and not come up with an entirely new configuration with multiple rings of detectors.

watch controller device that includes, among its various features, a touch screen, network interface, and storage device." Ex. 1003 ¶89. However, Dr. Kenny does not assert that Goldsmith cures the deficiencies in the proposed combination of Aizawa, Ohsaki, and Mendelson 2003. Thus, Dr. Kenny has not shown that claims 1 and 16 are obvious in view of Aizawa, Ohsaki, Mendelson 2003, and Goldsmith.

E. <u>The Challenged Dependent Claims Are Nonobvious Over Ground 1</u>

119. As discussed above, in my opinion claims 1 and 16 would not have been obvious over the cited references of Ground 1. In addition, in my opinion, the dependent claims would be nonobvious for at least the same reasons. *See* Sections VII.A-D, above.

120. In addition, for the reasons discussed below, dependent claims 9 and 15 are non-obvious for additional reasons. Claim 9 depends from claim 1 and includes the additional limitation: "wherein the single protruding convex surface protrudes a height between 1 millimeter and 3 millimeters." Claim 15 depends from claim 1 and adds the limitation: "wherein the single protruding convex surface protrudes a height greater than 2 millimeters and less than 3 millimeters." The '195 Patent provides that particular exemplary convex shapes improve signal strength. Ex. 1001 20:25-34. The '195 Patent discloses: "For example, in one embodiment, a convex bump of about 1 mm to about 3 mm in height and about 10

mm^2 to about 60 mm^2 was found to help signal strength by about an order of magnitude versus other shapes." Ex. 1001 20:29-33. Thus, the '195 Patent explains that an appropriately sized protrusion can dramatically increase the accuracy of the measurements. Ex. 1001 20:25-34.

121. Dr. Kenny identifies no corresponding teaching in Ohsaki, Aizawa, Mendelson 2003, or Goldsmith. Ex. 1003 ¶¶136-138, 163. Instead, Dr. Kenny states when "incorporating Ohsaki's teachings, a POSITA would have found it obvious that a device designed to fit on a user's wrist would be on the order of millimeters," and "there would have been a finite range of possible protruding heights, and it would have been obvious to select a protruding height that would have been comfortable to the user." Ex. 1003 ¶¶137-138. But nothing in the grounds references discloses a protrusion with a height either between 1 millimeter and 3 millimeters or greater than 2 millimeters and less than 3 millimeters would have been beneficial, as the inventors discovered.

122. Dr. Kenny suggests two references, Mendelson 2006 (Ex. 1016) and Mendelson 1988 (Ex. 1015), include disclosures of sensor sizes. Ex. 1003 ¶137. But neither Mendelson 2006 nor Mendelson 1988 disclose a cover, let alone a cover with a protrusion. Ex. 1016 Fig. 1 (no view of cover); Ex. 1015 Fig. 2B (showing flat layer of epoxy encapsulating optical components). The flat surface of encapsulating epoxy used with Mendelson 1988's sensor would not have

informed or motivated a POSITA to include a cover, much less a cover with a convex protrusion of a particular height.

123. Dr. Kenny seems to select Mendelson 2006 and Mendelson 1988 because they discuss similarly sized sensors (22 mm diameter and 19x19 mm square), which Dr. Kenny argues would also be used with a wrist-worn device. Ex. 1003 ¶137. But both Mendelson 2006 and Mendelson 1988 are forehead sensors, not wrist sensors. Ex. 1016 Abstract ("wireless wearable pulse oximeter developed based on a small forehead mounted sensor"); Ex. 1015 at 1 ("SpO_2 obtained from the forehead"). Dr. Kenny provides no basis to select one sensor size over another or select one protrusion height instead of any other. Indeed, Ohsaki explains that its sensor's width and length—including the board—are important but says nothing about the height of the board. *See* Ex. 1014 ¶[0019] ("the length of the detecting element 2 from the right side to the left side in FIG. 2 is longer than the length from the upper side to the lower side").

124. Dr. Kenny also cites Kondoh (Ex. 1028), which Dr. Kenny suggests "describ[es] a protrusion…that causes a subject's tissue to deform by a depth of about 2 to 20 mm." Ex. 1003 ¶137 (citing Ex. 1028). But Kondoh states the protrusion's height is 5 mm, which is outside of the claimed range. Ex. 1028 12:33-39, 13:51-55, 14:66-15:3, 16:15-19, 17:25-28, 26:10-14. In addition, Kondoh is contrary to the proposed cover because Kondoh embeds its optical

components (11, 12) on top of the "protrusion part" in direct contact with the user's skin (4). *See, e.g.,* Ex. 1028 13:62-64 ("placed in the protrusion"), Fig. 6. Contrary to Dr. Kenny's brief and unexplained citation, to the extent a POSITA would have found Kondoh relevant at all, Kondoh would have led a POSITA to eliminate any protruding convex surface on a cover so that the emitter and detector are placed as close as possible to—or in direct contact with—the body's surface. Ex. 1028 13:62-64 ("placed in the protrusion"), Fig. 6.

125. Dr. Kenny also offers testimony to support his assertions without citing specific evidence. Ex. 1003 ¶¶138, 163. In particular, Dr. Kenny provides no support for his opinion that a height either between 1 millimeter and 3 millimeters or greater than 2 millimeters and less than 3 millimeters "provide[s] a comfortable cover that prevents slippage." Ex. 1003 ¶138. Such unsupported testimony does not show that a POSITA would select a "single protruding convex surface protrudes a height between 1 millimeter and 3 millimeters" or a "single protruding convex surface protrudes a height greater than 2 millimeters and less than 3 millimeters." In my opinion, a POSITA would not have found it obvious to include a cover with a protruding convex surface where the "single protruding convex surface protrudes a height between 1 millimeter and 3 millimeters" or the "single protruding convex surface protrudes a height greater than 2 millimeters and less than 3 millimeters" based on the cited references of Ground 1.

Filed August 12, 2021

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

IPR2020-01737
Patent 10,709,366

PATENT OWNER RESPONSE

1. <u>Petitioner's Proposed Combination Changes Aizawa's Principle Of Operation And Eliminates A Feature Aizawa Repeatedly Identifies As Important</u>

Aizawa's approach monitors different individual detector signals and calculates pulse rate based on each individual photodetector signal. *See* Ex. 1006 ¶[0028] (referencing Figure 3 and explaining the pulse rate calculation for "the photodetector"); *see also id.* ¶¶ [0019] ("diagram of ***a*** pulse wave which is the output of ***a*** photodetector"), [0023], [0028] ("amplifying the outputs of the photodetectors," and "comput[ing] the number of outputs above the threshold value per unit time so as to calculate a pulse rate"); Ex. 2004 ¶102; Ex. 2026 76:13-22. Aizawa does not measure aggregated signals from detectors connected in parallel. *Id.* Instead, Aizawa repeatedly highlights that measuring pulse using a single detector's output helps address sensor dislocation. Ex. 1006 ¶¶[0027]-[0029], [0032], [0036]; *see also id.* ¶[0007] (discussing prior art where if the "position is dislocated, no output can be obtained"). Dr. Kenny confirmed Aizawa can detect a pulse rate based on the signal from just one photodetector. Ex. 2026 79:22-80:3. Aizawa also emphasizes that the detectors—regardless of number—"should be disposed around the light emitting diode 21 on a circle concentric to the light emitting diode 21 to detect a pulse wave." Ex. 1006 ¶[0032]; Ex. 2004 ¶102.

Petitioner ignores Aizawa's design and instead argues Mendelson 2003 would have motivated a POSITA to eliminate Aizawa's ability to monitor each detector

Filed June 28, 2022

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.

Petitioner,

v.

MASIMO CORPORATION,

Patent Owner.

IPR2020-01737
U.S. Patent 10,709,366

PATENT OWNER'S NOTICE OF APPEAL TO THE U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Pursuant to 28 U.S.C. § 1295(a)(4)(A), 35 U.S.C. §§ 141(c), 142, and 319, 37 C.F.R. §§ 90.2(a) and 90.3, and Rule 4(a) of the Federal Rules of Appellate Procedure, Patent Owner Masimo Corporation ("Masimo") hereby appeals to the United States Court of Appeals for the Federal Circuit from the Judgment – Final Written Decision (Paper 33) entered on May 4, 2022 (Attachment A) and from all underlying orders, decisions, rulings, and opinions that are adverse to Masimo related thereto and included therein, including those within the Decision Granting Institution of *Inter Partes* Review, entered May 12, 2021 (Paper 7). Masimo appeals the Patent Trial and Appeal Board's determination that claims 1-27 of U.S. Patent 10,709,366 are unpatentable, and all other findings and determinations, including but not limited to claim construction, as well as all other issues decided adverse to Masimo's position or as to which Masimo is dissatisfied in IPR2020-01737 involving Patent 10,709,366.

Masimo is concurrently providing true and correct copies of this Notice of Appeal, along with the required fees, to the Director of the United States Patent and Trademark Office and the Clerk of the United States Court of Appeals for the Federal Circuit.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 28, 2022

/Jarom Kesler/
Jarom D. Kesler (Reg. No. 57,046)

Attorney for Patent Owner
Masimo Corporation

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Jeroen Poeze	Nonprovisional Application Number (if known):	Herewith
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.
2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.
3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, <u>or</u> the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Scott Cromar/	Date 2020-03-25
Name (Print/Typed) Scott Cromar	Practitioner Registration Number 65066

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☑ *Total of 1 forms are submitted.

In regard to claim 18, Eastmond discloses preprocessing electronics (elements 102, 103, 104, 105, 106, 107, and 108, Fig. 1 and associated descriptions) and including at least: first preprocessing electronics configured to preprocess the first signal stream (elements 102, 104, 106, and 108, Fig. 1 and associated descriptions); and second preprocessing electronics configured to preprocess the second signal stream (elements 103, 105, 107, and 108, Fig. 1 and associated descriptions).

In regard to claim 19, Eastmond discloses the first preprocessing electronics comprise at least a first amplifier configured to receive the first signal stream and at least amplify the first signal stream (element 104, Fig. 1 and associated descriptions) and the second preprocessing electronics comprise at least a second amplifier configured to receive the second signal stream and at least amplify the second signal stream (element 105, Fig. 1 and associated descriptions).

In regard to claim 20, Eastmond discloses converting at least one of the first signal stream or the second signal stream from analog to digital (element 108, Fig. 1 and associated descriptions; element 108 receives analog signals from the two photodiode arrays and outputs binary encoded signal, Col 3 lines 11-40).

Allowable Subject Matter

6. Claims 2-14 and 30 are allowed.

7. The following is an examiner’s statement of reasons for allowance: Chaiken et al. (USPN 6,223,063 – applicant cited) teaches an optical tissue modulation device (Figs. 1-3) comprises one or more emitter (Fig. 2) and four photodiodes disposed on a

substrate (Fig. 1) and a cover with multiple protrusions placed on top of the photodiodes (Fig. 1). Kimura et al. (USPN 6,353,750 – applicant cited) teaches a noninvasive blood analyzer (Fig. 27) comprises one or more emitter (elements 11, Fig. 27), a photodiode array/ CCD (element 12, Fig. 27), and a cover with a protrusion (element 170, Fig. 27). However, the prior art of record does not teach or suggest "a first set of photodiodes arranged on the surface and spaced apart from each other, wherein: the first set of photodiodes comprises at least four photodiodes, and the photodiodes of the first set of photodiodes are connected to one another in parallel to provide a first signal stream responsive to light from at least one of the one or more light emitters attenuated by body tissue; a second set of photodiodes arranged on the surface and spaced apart from each other, wherein: the second set of photodiodes comprises at least four photodiodes, the photodiodes of the second set of photodiodes are connected to one another in parallel to provide a second signal stream responsive to light from at least one of the one or more light emitters attenuated by body tissue, and at least one of the first signal stream or the second signal stream includes information usable to determine a physiological parameter of a wearer of the noninvasive physiological parameter measurement device; a wall extending from the surface and configured to surround at least the first and second sets of photodiodes; and a cover arranged to cover at least a portion of the surface of the substrate, wherein the cover comprises a protrusion that extends over all of the photodiodes of the first and second sets of photodiodes arranged on the surface, and wherein the cover is further configured to cover the wall" and "a substrate having a surface; a first set of photodiodes arranged on the surface and spaced apart from each other, wherein: the first set of photodiodes comprises at least

four photodiodes, and the photodiodes of the first set of photodiodes are connected to one another in parallel to provide a first signal stream responsive to light from at least one of the one or more light emitters attenuated by body tissue; a second set of photodiodes arranged on the surface and spaced apart from each other, wherein: the second set of photodiodes comprises at least four photodiodes, the photodiodes of the second set of photodiodes are connected to one another in parallel to provide a second signal stream responsive to light from at least one of the one or more light emitters attenuated by body tissue; a wall extending from the surface and configured to surround at least the first and second sets of photodiodes; a cover arranged to cover at least a portion of the surface of the substrate, wherein: the cover comprises a protrusion that extends over all of the photodiodes of the first and second sets of photodiodes arranged on the surface, the protrusion comprises a convex protrusion, the cover is further configured to cover the wall, and the wall operably connects to the substrate on one side and operably connects to the cover on an opposite side", in combination with the other claimed elements/ steps.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

8. Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Notice of Allowability	**Application No.** 16/829,510	**Applicant(s)** Poeze et al.	
	Examiner CHU CHUAN LIU	**Art Unit** 3791	**AIA (FITF) Status** No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.☑ This communication is responsive to The TD filed on 05/06/2020 and the response filed on 05/07/2020.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2.☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3.☑ The allowed claim(s) is/are 2-15,17-20 and 22-30 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4.☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5.☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6.☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1.☐ Notice of References Cited (PTO-892)
2.☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 05/07/2020; 05/11/2020.
3.☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4.☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/CHU CHUAN LIU/ Examiner, Art Unit 3791	/ERIC F WINAKUR/ Primary Examiner, Art Unit 3791

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Poeze et al.	
U.S. Patent No.:	10,709,366	Attorney Docket No.: 50095-0027IP1
Issue Date:	July 14, 2020	
Appl. Serial No.:	16/829,510	
Filing Date:	March 25, 2020	
Title:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	

DECLARATION OF DR. THOMAS W. KENNY

Declaration

I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable under Section 1001 of Title 18 of the United States Code.

By: ______________________

Thomas W. Kenny, Ph.D.

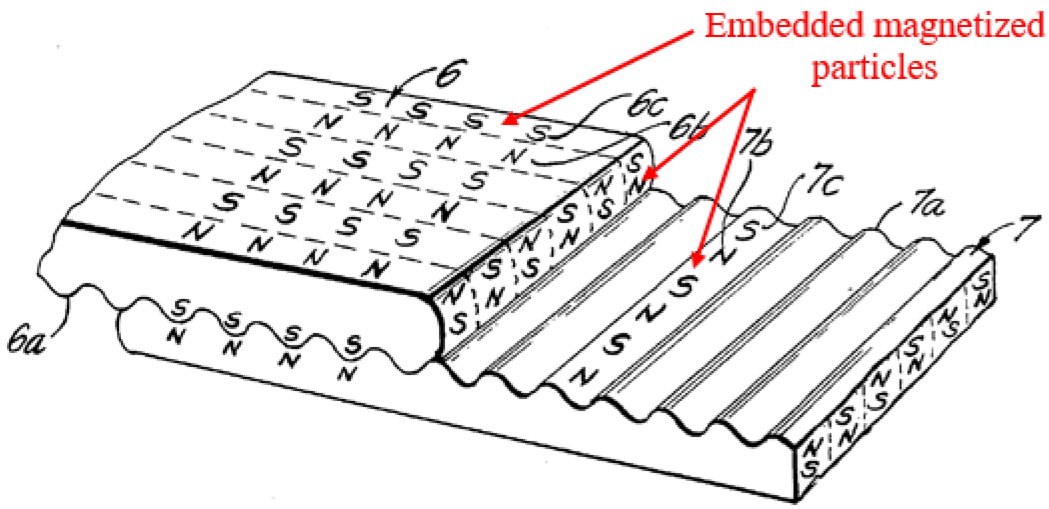


FIG.5

APPLE-1047, FIG. 2 (top), FIG. 5 (bottom)

VIII. GROUND 1 – Claims 1-12 and 14-27 Are Rendered Obvious by Aizawa in view of Mendelson-2003, Ohsaki, and Goldsmith

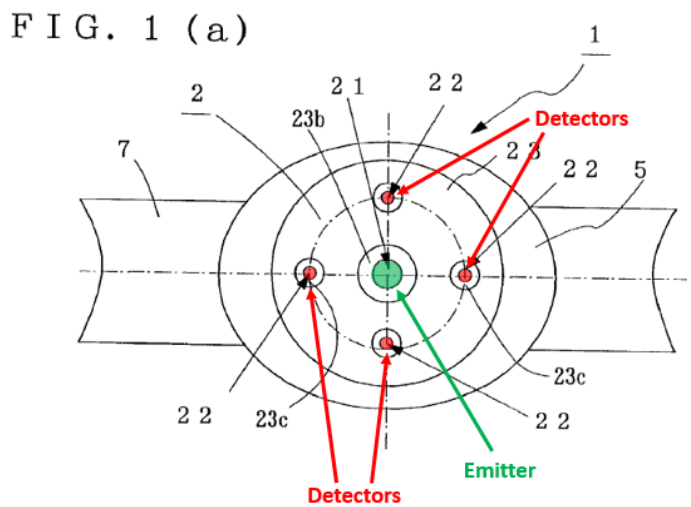
A. Combination of Aizawa, Mendelson-2003, Ohsaki, and Goldsmith

66. A POSITA would have been able and motivated to combine Aizawa, Mendelson-2003, Ohsaki, and Goldsmith in the manner described below to derive various benefits.

Aizawa + Mendelson-2003

67. As I described above in Section VII.A, Aizawa teaches a first set of photodiodes in the form of four photodetectors 22 that are circularly arranged around a centrally located emitter, as shown below. APPLE-1006, [0023].

Moreover, a signal stream from this first set of photodiodes is sent to a drive detection circuit 24 that "amplif[ies] the outputs of the photodetectors." *Id.*



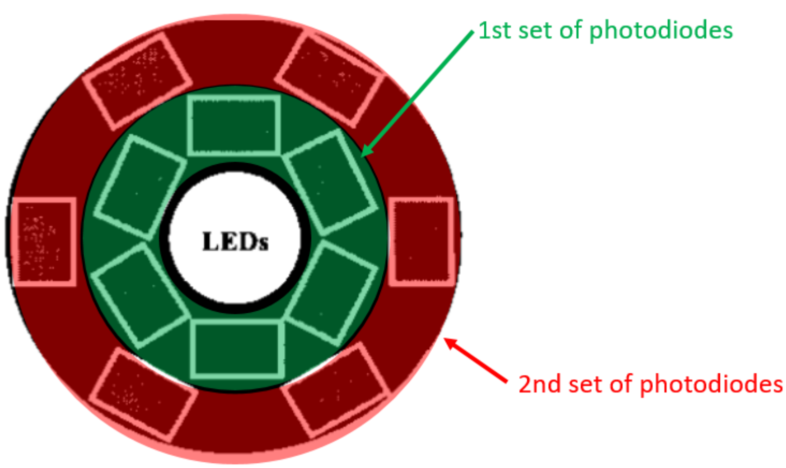
APPLE-1006, FIG. 1(a)

68. Aizawa teaches that 8 or more photodetectors may be provided to improve detection efficiency in some cases. *Id.*, [0032].

69. Aizawa does not expressly teach a second set of photodiodes that are connected to one another in parallel to provide a second signal stream as recited in claim 1 of the '366 patent. That is, while Aizawa teaches various ways of using a single ring of multiple detectors to improve detection efficiency, it does not explicitly mention that these multiple detectors may be provided as first and second sets of photodiodes that are each connected in parallel and provide first and second signal streams, respectively. APPLE-1006, [0013], [0030], [0032]. However, a POSITA would have realized that the arrangement of Aizawa's multiple detectors—which are arranged along a single ring—can be modified in

view of Mendelson-2003 to be instead arranged along two rings to provide a wider detection area, thereby further advancing Aizawa's goal of improving detection efficiency through increased power savings as taught by Mendelson-2003. APPLE-1006, [0013], [0030], [0032]; APPLE-1024, 3017, 3019.

70. For example, as I show below, Mendelson-2003 teaches using two rings of photodiodes/detectors ("near positioned" detectors highlighted in green, and "far positioned" detectors highlighted in red) where the detectors in each of the near and far rings are "***wired in parallel*** and connected through a central hub to the common summing input of a current-to-voltage converter." APPLE-1024, 3017. Mendelson-2003 further teaches that this configuration "widen[s] the active area of the PD which helps to collect a bigger portion of backscattered light intensity," thereby improving the light collection efficiency *Id.*, 3019. This configuration thus allows additional light to be captured, which in turn allows a lower brightness of LEDs to be used, which in turn would consume less power.



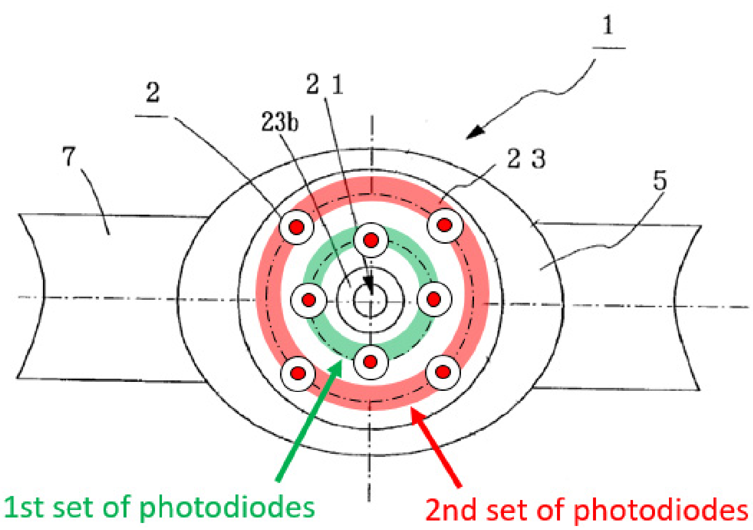
APPLE-1024, FIG. 1

71. Moreover, Mendelson-2003 is aimed at modifying conventional PD arrangements—***like that disclosed in Aizawa where a single ring of multiple PDs are mounted symmetrically around a light source***—to use two distinct rings of PDs that are mounted symmetrically around the light source. *See* APPLE-1024, 3016 (referring to conventional sensor designs based on "radial arrangement" of PDs or LEDs). Indeed, the prior art references mentioned in Mendelson-2003—*i.e.*, references [1]-[5]—describe conventional single ring devices such as those found in Mendelson-1988 (which corresponds to reference) and Aizawa. *See* APPLE-1015, 168, FIG. 2(A); APPLE-1006, [0032]. Mendelson-2003's 2-ring configuration thus allows additional light to be captured, which enables use of lower brightness LEDs (*i.e.*, LEDs driven by a lower driving current) while still achieving acceptable signals from the PDs. APPLE-1024, 3017, 3019.

72. A POSITA in possession of both Aizawa and Mendelson-2003 would have recognized Mendelson-2003's use of two concentric rings (one that is near-positioned and another that is far-positioned) of photodiodes as a desirable detector configuration that would reap similar benefits for Aizawa in terms of achieving "power savings in the design of a more efficient" pulse sensing device. APPLE-1024, 3017. By using Mendelson-2003's power-saving (*i.e.*, efficiency-enhancing)

PD configuration, the power consumption of a wrist-based pulse sensing device as in Aizawa can be reduced through use of a less bright and, hence, lower power-consuming LED. This would in turn allow Aizawa's wrist-based device to have a longer battery life. *Id.*

73. An example implementation of adding an additional ring of detectors to Aizawa, as per the teachings of Mendelson-2003, is shown below:



APPLE-1006, FIG. 1(a)

74. A POSITA would have further realized, in view of Mendelson-2003, that such a two-ring arrangement can be implemented in a wrist sensor device as in Aizawa by wiring each ring of detectors in parallel and summing the input of their respective streams. APPLE-1024, 3017; *see also* APPLE-1042, 5:20-67, FIGS 1-2; APPLE-1025, 4:23-30.

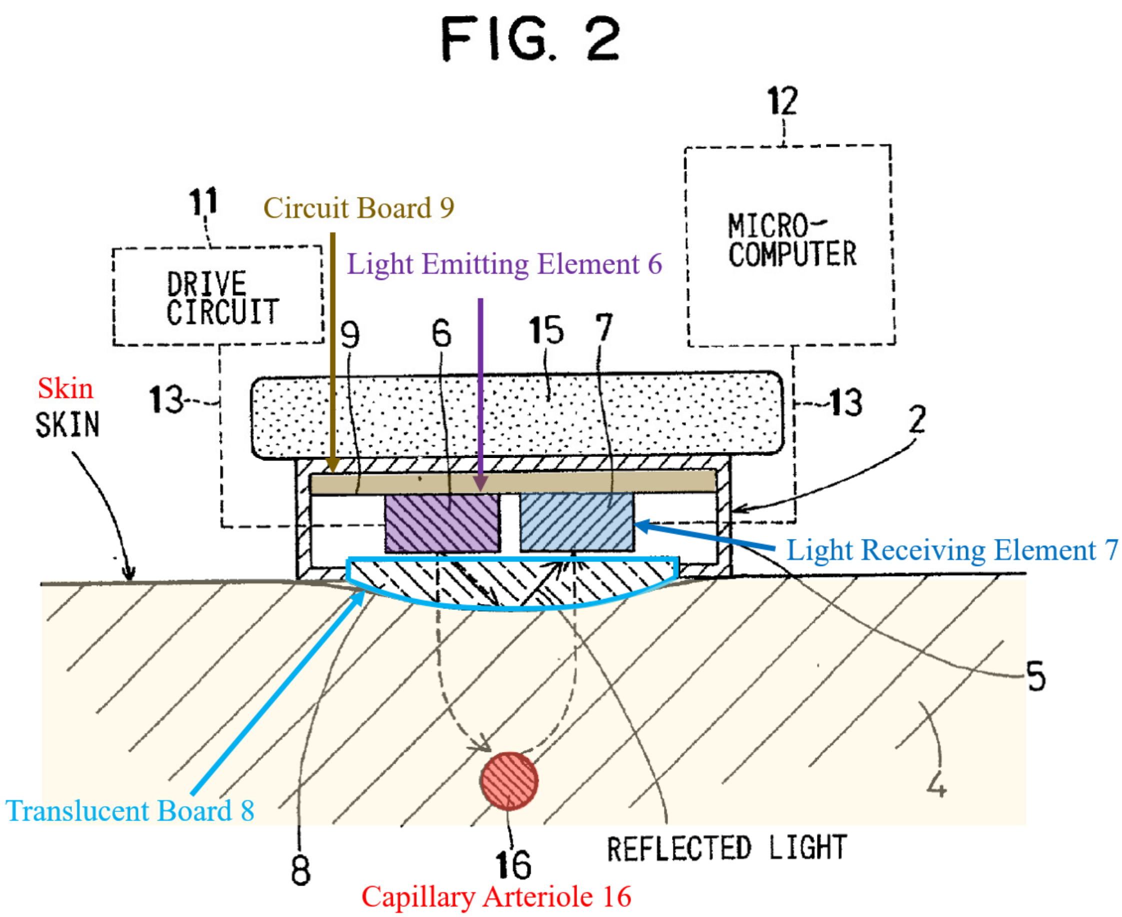
75. A POSITA also would have found it obvious to modify Aizawa with Mendelson-2003 to add an additional ring of detectors because doing so merely involves the use of known solutions to improve similar systems and methods in the same way. For instance, a POSITA would have recognized that applying Mendelson-2003's teachings regarding two, concentric rings of detectors that are each connected in parallel to Aizawa's sensor would have led to predictable results without significantly altering or hindering the functions performed by Aizawa's sensor. A POSITA would have been motivated to provide the well-known feature of providing multiple rings of detectors to a pulse sensor to achieve the predictable benefits offered by Mendelson-2003's description of the same. In fact, Aizawa itself contemplates, and is thus capable of supporting, the addition of extra detectors to improve light collection efficiency, although it does not disclose whether they may be arranged as two concentric rings. APPLE-1006, [0032]. Moreover, as noted above, Mendelson-2003 expressly contemplates adding an additional ring of detectors to a conventional 1-ring PD arrangement precisely as found in Aizawa. APPLE-1024, 3016.

<u>Aizawa + Mendelson-2003 + Ohsaki</u>

76. A POSITA would have been able and motivated to *further* combine the teachings of Aizawa-Mendelson-2003 with the teachings of Ohsaki such that the

cover of Aizawa-Mendelson-2003's wrist-worn sensor would include a convex surface, improving adhesion between a subject's wrist and a surface of the sensor. APPLE-1014, [0025] (the convex surface prevents slippage of the detecting element from its position on the subject's wrist, and the convex nature of the surface suppresses the "variation of the amount of the reflected light" that reaches the detecting element).

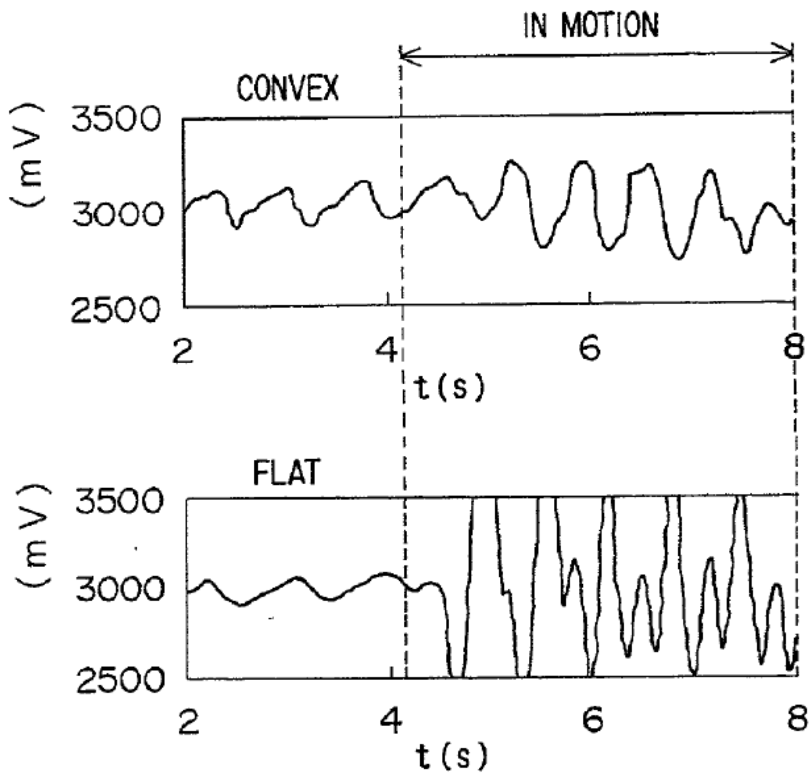
77. In particular, Ohsaki describes a "detecting element" that includes "a package 5, a light emitting element 6 (e.g., LED), a light receiving element 7 (e.g., PD), and a translucent board 8." APPLE-1014, [0017]. "The package 5 has an opening and includes a" substrate in the form of "circuit board 9," on which light emitting element 6 and light receiving element 7 are arranged. *Id.*. As I show below in Ohsaki's FIG. 2, translucent board 8 is arranged such that, when the sensor is worn "on the user's wrist … the convex surface of the translucent board … is in intimate contact with the surface of the user's skin"; this contact between the convex surface and the user's skin is said to prevent slippage, which increases the strength of the signals obtainable by Ohsaki's sensor. APPLE-1014, [0015], [0017], [0025], FIGS. 1, 2, 4A, 4B.



APPLE-1014, FIG. 2 (annotated)

78. Here, Ohsaki explains that "if the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist as shown in FIG. 4B (reproduced below)," but that if "the translucent board 8 has a convex surface…variation of the amount of the reflected light…that reaches the light receiving element 7 is suppressed." APPLE-1014, [0025]. The convex surface is also said to prevent "disturbance light from the outside" from penetrating translucent board 8. *Id*. Thus, when a convex cover is used, "the pulse wave can

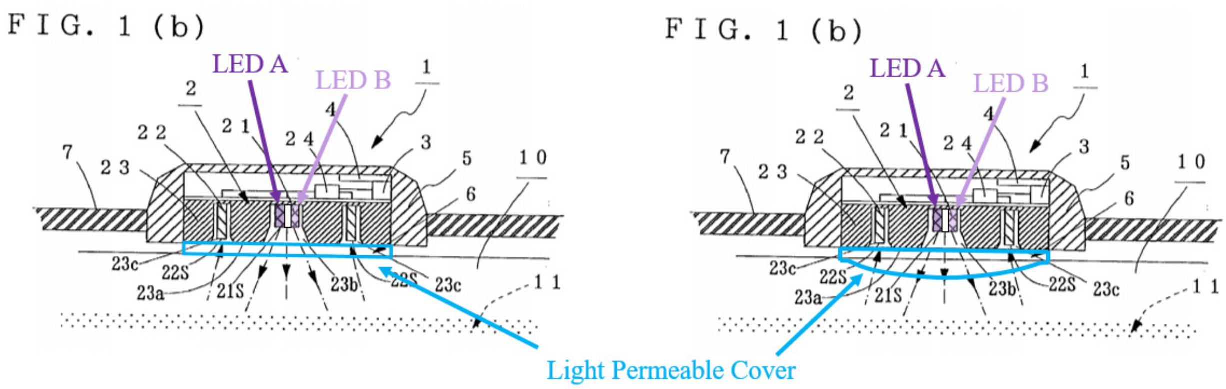
be detected without being affected by the movement of the user's wrist 4 as shown in FIG. 4A." *Id.*



APPLE-1014, FIGS. 4A, 4B

79. Thus, as I show below, a POSITA would have found it obvious to modify the sensor's flat cover (left) to include a lens/protrusion (right), similar to Ohsaki's translucent board 8, so as to improve adhesion between the user's wrist and the sensor's surface, improve detection efficiency, and protect the elements within the sensor housing. APPLE-1014, [0025] (explaining that the convex surface of translucent board 8 prevents slippage of a detecting element from its position on

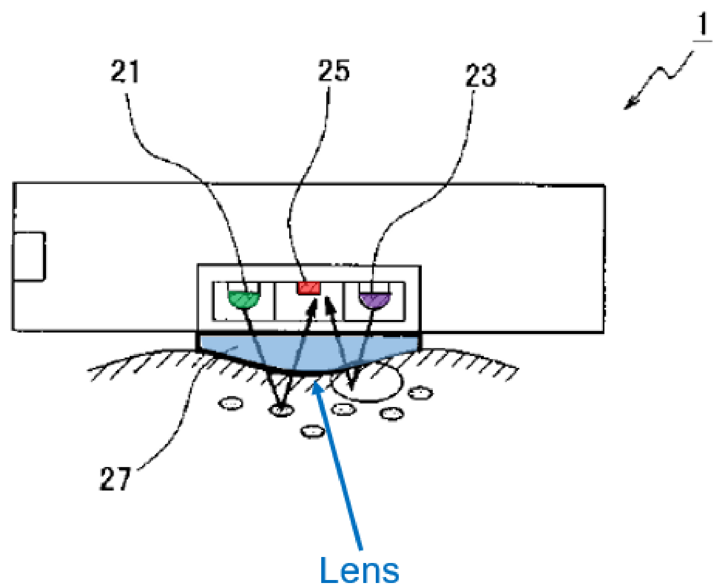
the wrist, and suppresses the "variation of the amount of the reflected light" that reaches the detecting element).



APPLE-1006, FIG. 1(b)

80. A POSITA would have combined the teachings of Aizawa-Mendelson-2003 and Ohsaki as doing so would have amounted to nothing more than the use of a known technique to improve similar devices in the same way. For instance, a POSITA would have recognized that incorporating Ohsaki's convex surface is simply improving Aizawa-Mendelson-2003's transparent plate 6 that has a flat surface to improve adhesion to a subject's skin and reduce variation in the signals detected by the sensor. Furthermore, the elements of the combined system would each perform similar functions they had been known to perform prior to the combination. That is, Aizawa-Mendelson-2003's transparent plate 6 would remain in the same position, performing the same function, but with a convex surface as taught by Ohsaki.

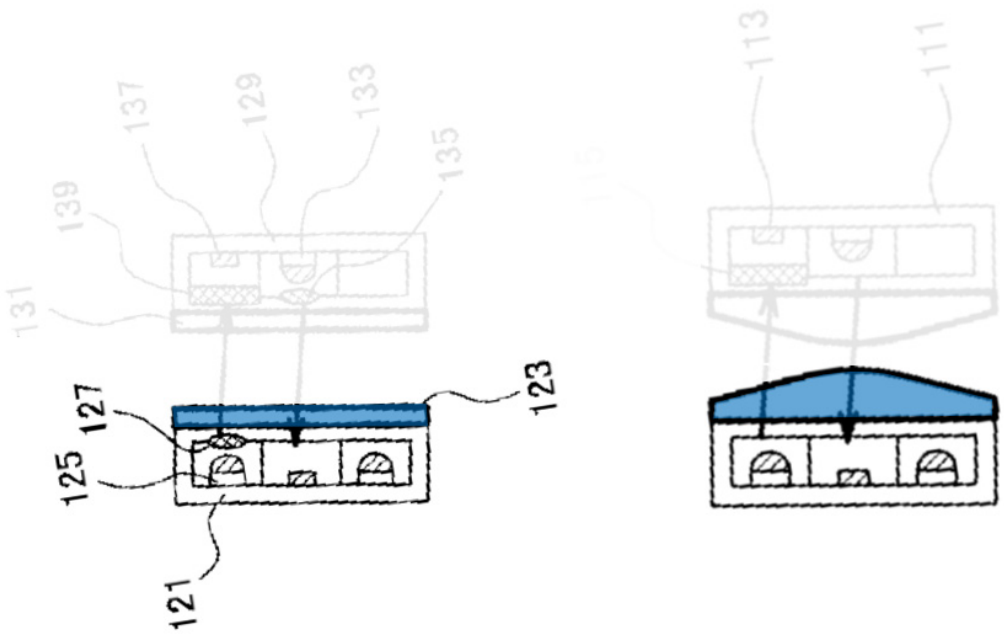
81. Incidentally, Inokawa provides further rationale for a POSITA to modify Aizawa to include a cover comprising a protruding convex surface, thus further strengthening the combination I just described above. For example, as shown below, Inokawa discloses a side lens 27:



APPLE-1008, FIG. 2

82. Inokawa further teaches that the "lens makes it possible to increase the light-gathering ability of the LED." APPLE-1008, [0015]. Thus, a POSITA would have understood that adding a protruded convex surface to Aizawa would have the additional benefit of increasing light collection efficiency, which would in turn lead to an improved signal-to-noise ratio and more reliable pulse detection. The lens of Inokawa provides precisely such an additional benefit to Aizawa's device by refracting/concentrating incoming light signals reflected by the blood. *Id.*

83. A POSITA would have further understood, in view of Inokawa, *how* to implement the convex surface of Ohsaki into Aizawa. For example, as shown below, Inokawa teaches that its cover may be either flat (left) such that "the surface is less prone to scratches," Inokawa at [0106], or in the form of a lens (right) to "increase the light-gathering ability of the LED." APPLE-1008, [0015].



APPLE-1008, FIG. 17 (left), FIG. 16 (right)

84. A POSITA would have further recognized that the transparent acrylic material used to make Aizawa's plate can be readily formed to have a convex shape as in Inokawa. *See* APPLE-1009 at 3:46-51, FIG. 1.

<u>**Aizawa + Mendelson-2003 + Ohsaki + Goldsmith**</u>

85. A POSITA would have been able and motivated to further modify Aizawa-Mendelson-2003-Ohsaki in view of Goldsmith to achieve various additional benefits. In particular, Aizawa acknowledges an interest in real-time heart rate measurement "at the time of exercise," and describes its wrist-worn pulse wave sensor as being "easily attached," and "capable of detecting a pulse wave accurately." APPLE-1006, [0004], [0008]. Aizawa also says that its sensor includes "a transmitter for transmitting…pulse rate data to an unshown display," and that its "pulse rate detector…can be coupled to devices making use of bio signals." APPLE-1006, [0023], [0035]. Accordingly, a POSITA would have understood that Aizawa's sensor transmits data to a display and/or another device to which that sensor is coupled. Moreover, the above-noted and related disclosure would have motivated a POSITA to implement Aizawa's pulse rate sensor as part of a comprehensive monitoring device that can monitor and display heart rate during exercise. APPLE-1006, [0004], [0008], [0023], [0026], [0035], FIGS. 1(a), 1(b), 2.

86. As explained above in Section VII.D, Goldsmith describes a watch controller device that can be used with diagnostic devices including sensors to obtain, display, and communicate physiological measurements such as user temperature heart rate. APPLE-1027, [0082]-[0084], [0095], [0037], [0038], claims 25, 26. Goldsmith's device has a wrist band and can be worn like a watch

such that it can monitor and display data "received from a sensor transmitter on the patient's skin" and "communicate with a remote station." APPLE-1027, [0085], [0087], [0089], [0095], FIGS. 9A, 9B, 10.

87. From this and related disclosure, a POSITA would have understood that Goldsmith's device is capable of receiving heart rate data directly from the transmitter in Aizawa's sensor, which is worn on the user's skin, and that Goldsmith's device can both display that data on its included touch-screen display, and wirelessly communicate that data to additional devices, including cellular phones, for remote monitoring. APPLE-1027, [0017], [0034], [0036], [0082]-[0085], [0087]-[0089], [0095], [0097], FIGS. 9A, 9B, 10; APPLE-1006, [0023], [0026], FIGS. 1(a), 1(b), 2.

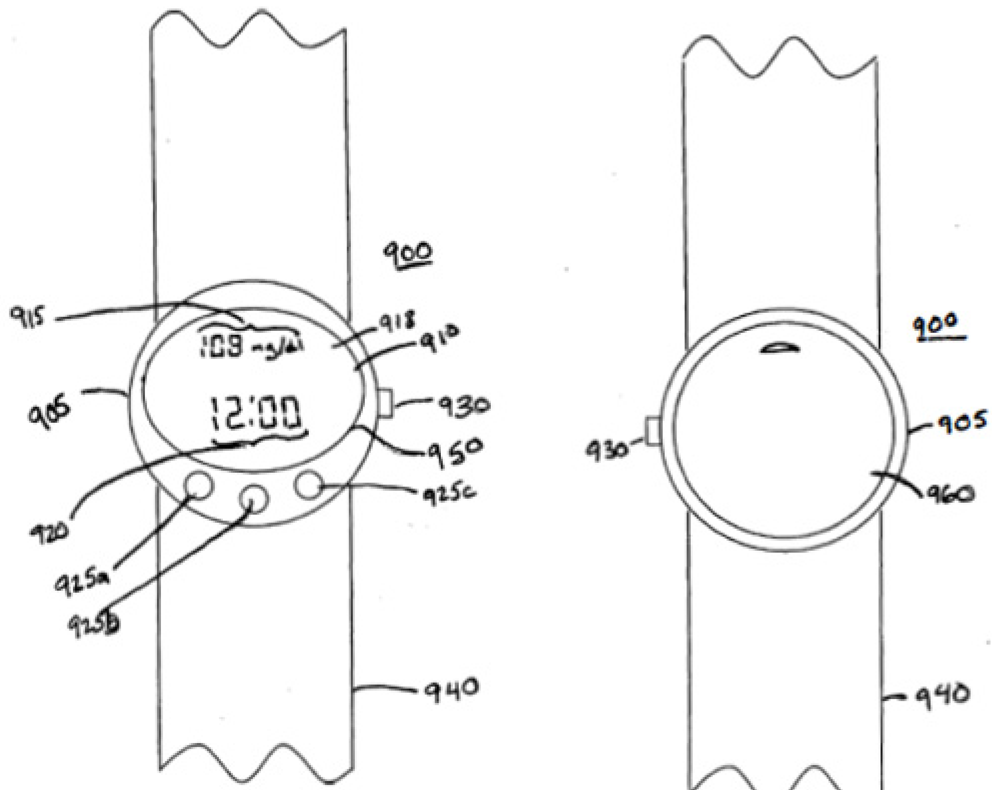
88. As explained in more detail below, a POSITA would have found it obvious to incorporate Aizawa's wrist-worn pulse wave sensor with (i) two rings of photodiodes each connected in parallel (as per Mendelson-2003) and (ii) a protruding convex surface (as per Ohsaki) into Goldsmith's integrated wrist-worn watch controller device that includes, among its various features, a touch screen, network interface, and storage device. APPLE-1027, FIG. 10, [0085]-[0088], [0090]-[0095], [0102], [0104], [0011], [0013], [0014], [0018], [0022]-[0024], [0035], [0043], [0046], [0050], [0052], FIGS. 8, 10, claims 5, 9, 10, 12, 13, 26, 43-45, 53.

89. Goldsmith states that its watch device may receive data "directly from a sensor transmitter on the patient's skin," adding that "the controller device may monitor heart rate," and a POSITA would have understood that Goldsmith's heart rate sensor could be implemented by integrating the Aizawa-Mendelson-2003-Ohsaki sensor into Goldsmith's watch controller device, which would have enhanced the sensor's utility and improved the user's experience in many ways. APPLE-1027, [0087], [0095]. For example, a POSITA would have incorporated the Aizawa-Mendelson-2003-Ohsaki sensor into Goldsmith's watch device to enable a user to view and interact with heart rate data during exercise via the Goldsmith's touch-screen display, and to enable heart rate data to be monitored by the user and/or others through any of the devices with which Goldsmith's device can communicate. APPLE-1006, [0004], [0035]; APPLE-1027, [0017], [0034], [0036], [0082]-[0085], [0087]-[0089], [0095], [0097], FIGS. 9A, 9B, 10.

90. Moreover, a POSITA would have understood that incorporating the Aizawa-Mendelson-2003-Ohsaki sensor into Goldsmith's device would have amounted to nothing more than the use of a known technique to improve similar devices in the same way, and combining prior art elements according to known methods to yield predictable results. *See, e.g.,* APPLE-1044, Abstract ("A wrist-worn apparatus for monitoring a user's performance…includes…a processor, a heart rate monitor, a timer, a user input, a display, a processor and a memory"), 3:57-4:11 ("User input

11 may comprise…a touch screen"), FIGS. 1, 2. Further, any modifications to the dimensions to Goldsmith's watch controller device needed to accommodate Aizawa-Mendelson-2003-Ohsaki's sensor would have been mere design choice options as often is the case when making body-worn devices. Indeed, the '366 patent evidences that integrating a PMD like Aizawa-Ohsaki's sensor with a touchscreen, as disclosed in Goldsmith, would have been well within the skill set of a POSITA—the '366 patent mentions a "touch-screen display" in passing among a laundry list of potential displays with the understand that such integration would have been known to a POSITA. APPLE-1001, 15:57-61, 17:20-26.

91. As illustrated below, the front side of Goldsmith's device features a display 910, and the rear side includes a cover 360. APPLE-1027, [0030]-[0031], [0085].

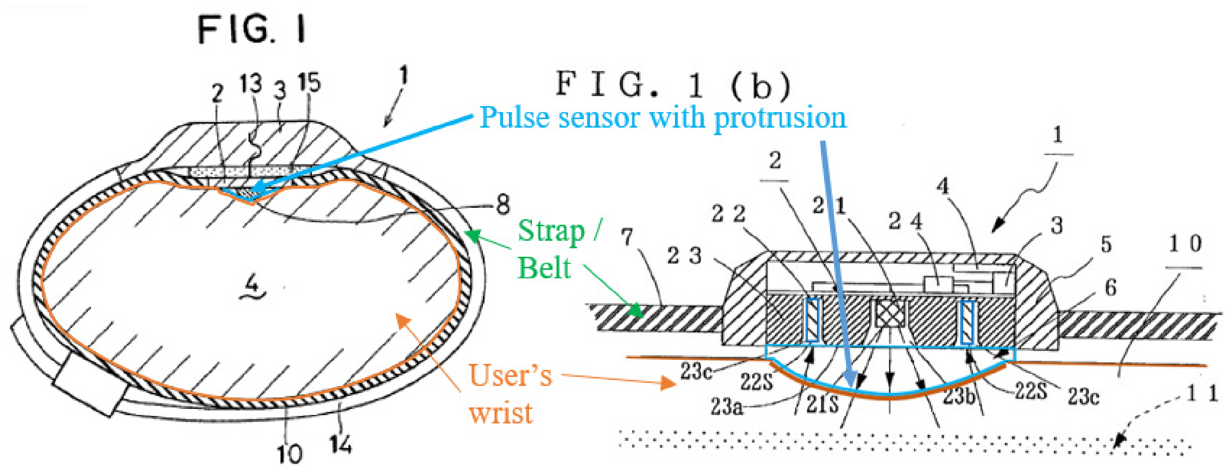


Front side (facing away from the wrist) Rear side (facing the wrist)

FIG. 9A FIG 9B

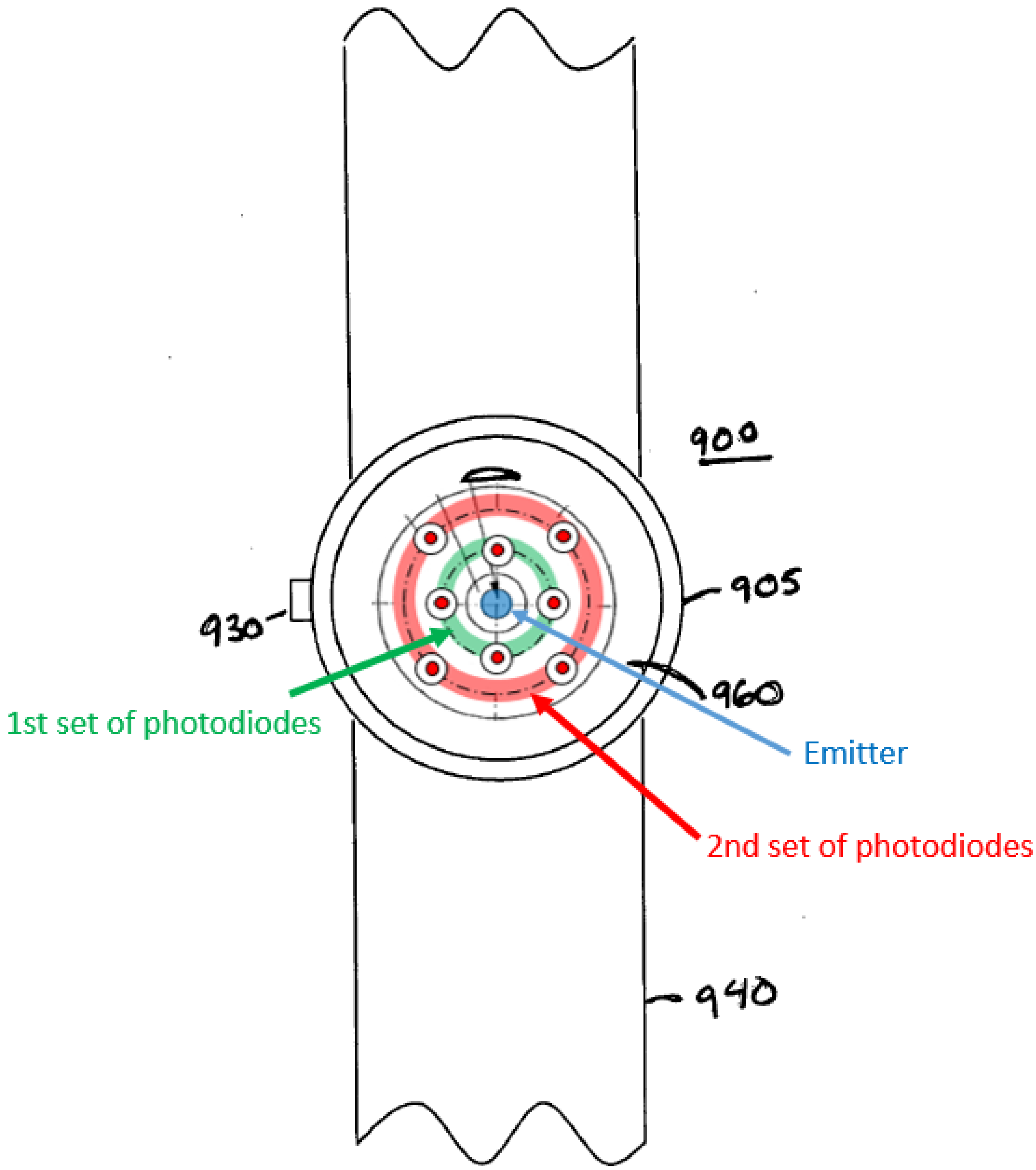
APPLE-1027, FIGS. 9A, 9B.

92. As illustrated below, the rear side of the sensor in both Aizawa and Ohsaki includes an emitter, detectors, and a cover with a protruding convex surface facing the user's wrist, which enables light to be emitted onto the user's skin and to be detected after attenuation.



APPLE-1014, FIG. 1 (left), APPLE-1006, FIG. 1(b) (right).

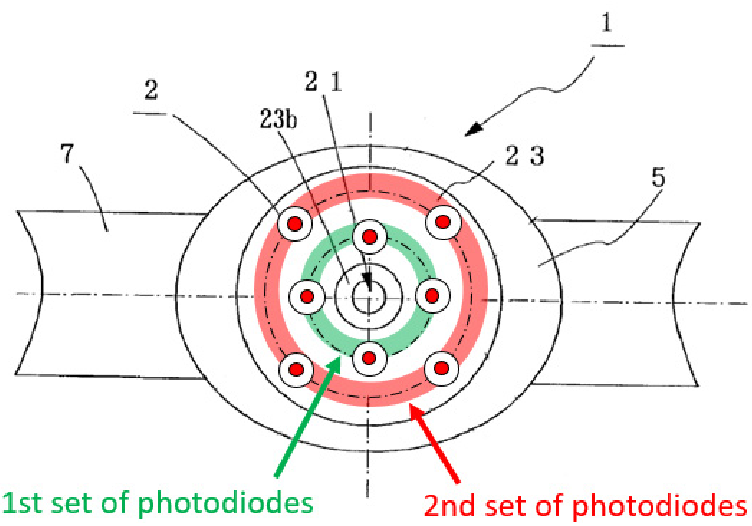
93. Consistent with Aizawa, Ohsaki, and Goldsmith's disclosures, a POSITA would have found it obvious to incorporate the Aizawa-Mendelson-2003-Ohsaki sensor into the rear side of Goldsmith's watch device, such that the included emitter and detectors face the user's skin. APPLE-1006, [0023]-[0027], FIGS. 1(a), 1(b), 2; APPLE-1014, FIGS. 1, 2; APPLE-1027, [0087]. An exemplary implementation of the resulting physiological monitoring device is shown in the figure below. Other components disclosed by Goldsmith, such as the network interface, transceiver, and storage device, would have been located within the modified device's housing, *e.g.*, between the touch-screen display and the substrate supporting the detectors. APPLE-1027, FIGS. 8, 10.



APPLE-1027, FIG. 9B (modified according to APPLE-1006)

B. Claim 1

[1pre]: A noninvasive physiological parameter measurement device adapted to be worn by a wearer, the noninvasive physiological parameter measurement device comprising:



APPLE-1006, FIG. 1(a)

[1e]: the photodiodes of the first set of photodiodes are connected to one another in parallel to provide a first signal stream responsive to light from at least one of the one or more light emitters attenuated by body tissue;

101. As I discussed above in Section VIII.A, Aizawa-Mendelson-2003-Ohsaki-Goldsmith renders obvious first and second sets of photodiodes. As explained further below, POSITA would have recognized and/or found it obvious that the first set of photodiodes are connected to one another in parallel to provide a first signal stream.

102. First, a POSITA would have recognized and/or found it obvious that an array of photodiodes, as found in the first set/ring of photodiodes in the modified Aizawa device, would be connected to one another in parallel to thereby form, essentially, a single continuous detector. APPLE-1025, 4:23-30. Indeed, a

POSITA would have recognized that connecting multiple photodiodes together in parallel allows the current generated by the multiple photodiodes in the first set/ring to be added to one another, thereby resulting in a larger total current akin to what would be generated from a single, large detector, which is what the ring of detectors in Aizawa is in effect trying to mimic. This is an elementary concept in photosensor circuit design.

103. Second, Mendelson-2003, whose sensitivity-enhancing photodiode arrangement configuration is being used to modify Aizawa, expressly teaches that the photodiodes in each of the two sets (*i.e.*, rings) of photodiodes are connected to one another in parallel, thereby providing a distinct signal stream for each set/ring. In particular, Mendelson-2003 teaches that "[e]ach cluster of six PDs were wired in parallel and connected through a central hub to the common summing input of a current-to-voltage converter." APPLE-1024, 3017. Thus, as described above in Section VIII.A, a POSITA seeking to add a second ring of photodiodes to Aizawa would have looked to Mendelson-2003's teachings concerning how the two rings of photodiodes in the modified Aizawa device should be wired. Thus, a POSITA would have found, in view of Mendelson-2003's express teachings, wiring two rings of photodiodes such that each ring/set of detectors "were wired in parallel" to be a routine and conventional design choice. Indeed, connecting photodiodes in a first set of photodiodes to one another in parallel to provide a first signal stream, as

evidenced by Mendelson-2003, was common practice well before the Critical Date, and there was nothing new or inventive about changing the way such photodiodes are connected. *See* APPLE-1025, 4:23-30.

104. Moreover, a POSITA would have recognized that there can be multiple benefits to separately transmitting signals streams from the near and far detectors—as opposed to combining all the signals from the detectors into a single stream. For example, Mendelson ’799 teaches that the detected values from each of its near and far detector arrays can be monitored such that “if both of them are not in the mentioned range, a corresponding alarm is generated indicative of that the sensor position should be adjusted.” APPLE-1025, 13:19-30, FIG. 10A. In other words, monitoring each signal stream (from each ring of detectors) separately allows the system to determine when the sensor device is so severely located that its position should be adjusted. Mendelson ’799 also teaches that its detector configuration can help detect “movement/breathing artifacts” and subsequently generate “a corresponding alarm signal.” APPLE-1025, 13:31-42. Mendelson ’799 is able to achieve this (along with other benefits) by maintaining separate streams coming from each of its inner and outer rings of photodetectors. *Id.* Having two separate signal streams can also offer various advantages during research, testing, and/or calibration scenarios, where the ability to monitor each

stream separately can be beneficial, for instance, to ensure that both rings are performing properly.

105. Additionally, a POSITA would have known that "[t]he intensity of the backscattered light decreases in direct proportion to the square of the distance between the photodetector and the LEDs." APPLE-1015, 168. In other words, a POSITA would have recognized that the photodiodes in the far ring (*i.e.,* second set of photodiodes) would receive reflected light having a lower intensity than that received by the photodiodes in the near ring (*i.e.*, first set of photodiodes) and would have been motivated and found it obvious to account for this discrepancy. Indeed, as shown in the plot below, "the light intensity detected by the photodiode decreases roughly exponentially as the radial distance from the LED's is increased." APPLE-1017, 801. This is because "the probability that the incident photons will be absorbed as they traverse a relatively longer path length before reaching the detector is increased." *Id.*

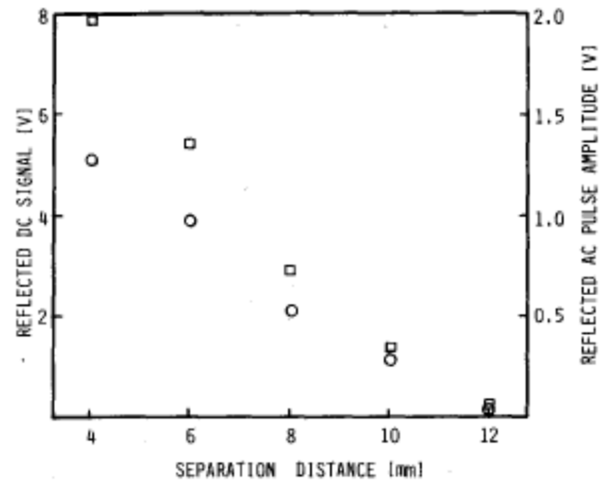


Fig. 4. The effect of LED/photodiode separation on the dc (□) and ac (○) components of the reflected infrared photoplethysmograms. Measurements were performed at a skin temperature of 43°C.

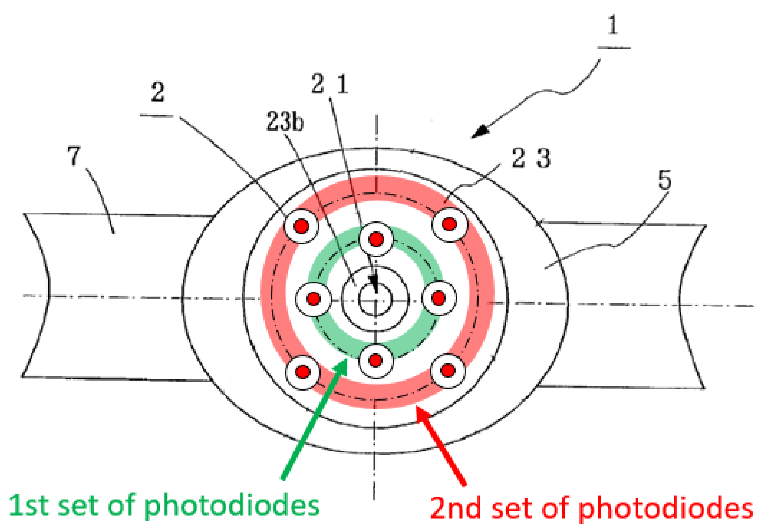
APPLE-1017, FIG. 4.

106. In Aizawa, a "drive detection circuit 24" is used for "amplifying the outputs of the photodetectors" and transmitting the amplified data to the arithmetic circuit 3, which computes the pulse rate. APPLE-1006, [0023], [0028]. In the modified Aizawa-Mendelson-2003 system, a POSITA would have recognized that the inner ring is likely to produce far greater currents compared to the outer ring due to the above-noted exponential relationship between detected light intensity and distance from the LED. APPLE-1017, 801. To ensure that the pulse rate data provided by the outer ring is preserved when combined with the pulse rate data provided by the inner ring, a POSITA would have found it obvious, in some implementations, to keep each ring separately wired and connected to its own amplifier (*i.e.*, drive detection circuit 24) to thereby keep the magnitude of the current signals provided by each ring approximately the same before being combined and transmitted to the

arithmetic circuit 3. Otherwise, if all the photodiodes in both the first and second rings in the modified Aizawa's sensor device are connected together in parallel such that a single stream is output (from both rings) to a single amplifier, signals detected by the near/first sets of detectors may drown out the weaker signals coming from the far/second sets of detectors, thereby diminishing the enhanced sensitivity and collection efficiency achieved through the widened detection area.

[1f]: a second set of photodiodes arranged on the surface and spaced apart from each other, wherein:

107. As discussed above in Section VIII.A and shown below, the Aizawa-Mendelson-2003-Ohsaki-Goldsmith device includes a second set of photodiodes (red ring):



APPLE-1006, FIG. 1(a)

108. As discussed above for element [1c], the photodiodes in the combination are arranged on the surface and spaced apart from each other:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Poeze et al.	
U.S. Patent No.:	10,709,366	Attorney Docket No.: 50095-0027IP1
Issue Date:	July 14, 2020	
Appl. Serial No.:	16/829,510	
Filing Date:	Mar. 25, 2020	
Title:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	

SECOND DECLARATION OF DR. THOMAS W. KENNY

I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of the Title 18 of the United States Code.

Dated: November 10, 2021 By: ________________________

Thomas W. Kenny, Ph.D.

experience, including my work experience in the fields of mechanical engineering, computer science, biomedical engineering, and electrical engineer; my experience in teaching those subjects; and my experience in working with others involved in those fields. In addition, I have analyzed various publications and materials, in addition to other materials I cite in my declaration.

6. My opinions, as explained below, are based on my education, experience, and expertise in the fields relating to the '366 Patent. Unless otherwise stated, my testimony below refers to the knowledge of one of ordinary skill in the fields as of the Critical Date, or before.

II. Ground 1

7. As I explained at length in my first declaration, a POSITA "would have found it obvious to modify the [Aizawa] sensor's flat cover…to include a lens/protrusion…similar to Ohsaki's translucent board 8, so as to [1] improve adhesion between the user's wrist and the sensor's surface, [2] improve detection efficiency, [3] and protect the elements within the sensor housing." APPLE-1003, ¶¶79-84. Rather than attempting to rebut my testimony on these points, Masimo and its witness, Dr. Madisetti, responded with arguments that are technically and factually flawed.

8. Specifically, Masimo contends that "Ohsaki and Aizawa employ different sensor structures (rectangular versus circular) for different measurement locations (back side versus palm side of the wrist), using different sensor surface shapes (convex versus flat) that are tailored to those specific measurement locations" and from this concludes that "[a]

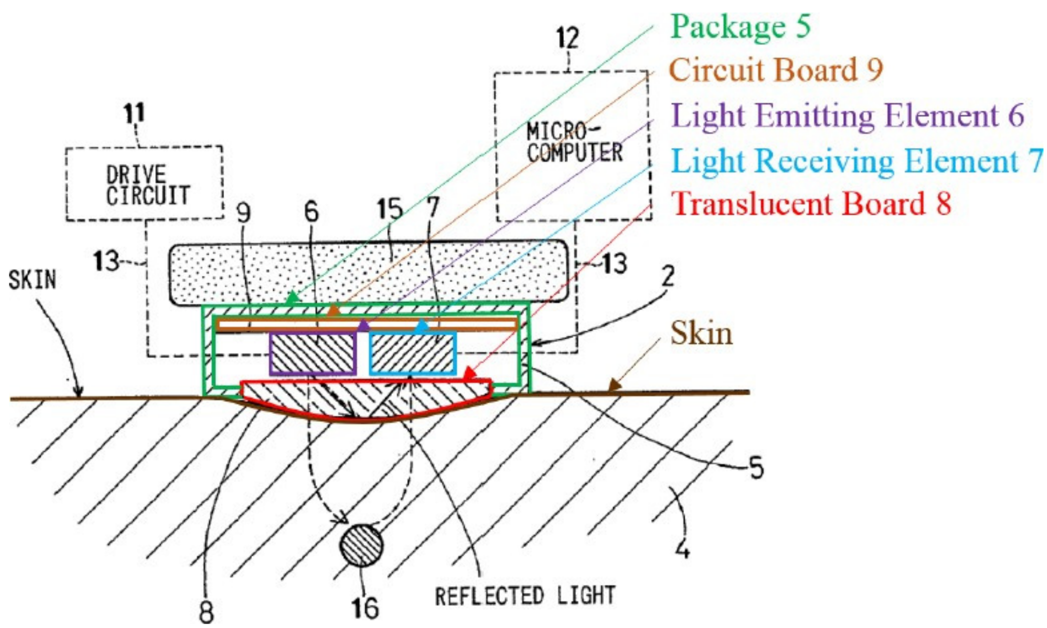
POSITA would [not] have been motivated to combine the references and reasonably expected such a combination to be successful." IPR2020-01733, Pap. 15 ("**POR**"), 1-3.

9. In this way and as I explain in further detail, the POR avoids addressing the merits of the combinations advanced in Apple's Petition, relies on mischaracterizing the prior art combinations and my testimony, and ignores the inferences and creative steps that a POSITA would have taken when modifying Aizawa's sensor to achieve the benefits taught by Ohsaki and Mendelson-2003, among others.

10. Contrary to Masimo's contentions, Ohsaki does not limit its benefits to a rectangular sensor applied to a particular body location, and a POSITA would not have understood those benefits as being so limited. For example, Ohsaki teaches that "the detecting element and the sensor body 3 may be worn on the back side of the user's forearm" or wrist. Nowhere does Ohsaki teach that its sensor can only be worn on a particular body location. APPLE-1014, [0030], [0008]-[0010], Abstract. In its summary of invention and claim preambles, Ohsaki explains that the object of its invention is "to provide a human pulse wave sensor which is capable of detecting the pulse wave ***of a human body*** stably and has high detection probability." APPLE-1014, [0007], claims 1-8. Thus, Ohsaki's disclosure should not be narrowly understood as applying to a single location or a single embodiment. Aizawa similarly reveals an embodiment in which its sensor is located on the palm side of the wrist (*see* APPLE-1006, FIG. 2, [0002], [0009]), but does not limit its sensor to being applied to just the palm side of the wrist. A POSITA, based on Aizawa and Ohsaki's disclosure, would have understood that the sensors in Aizawa and Ohsaki, when combined

in the manner explained in my earlier declaration, would have been applicable to various locations on a human body and would have improved the performance of the sensor by providing the benefits described in these disclosures. Indeed, a POSITA would understand that the claimed benefits of the detector arrangement and the convex cover would have been useful and beneficial for measurements on many other locations.

11. In addition to the above, as shown in Ohsaki's FIG. 2 (reproduced below), Ohsaki attributes the reduction of slippage afforded by use of translucent board 8 (and additional related improvements in signal quality) to the fact that "***the convex surface of the translucent board…is in intimate contact with the surface of the user's skin***"[1] when the sensor is worn. APPLE-1003, ¶77; APPLE-1014, [0015], [0017], [0025], FIGS. 1, 2, 4A, 4B.



APPLE-1014, FIG. 2 (annotated).

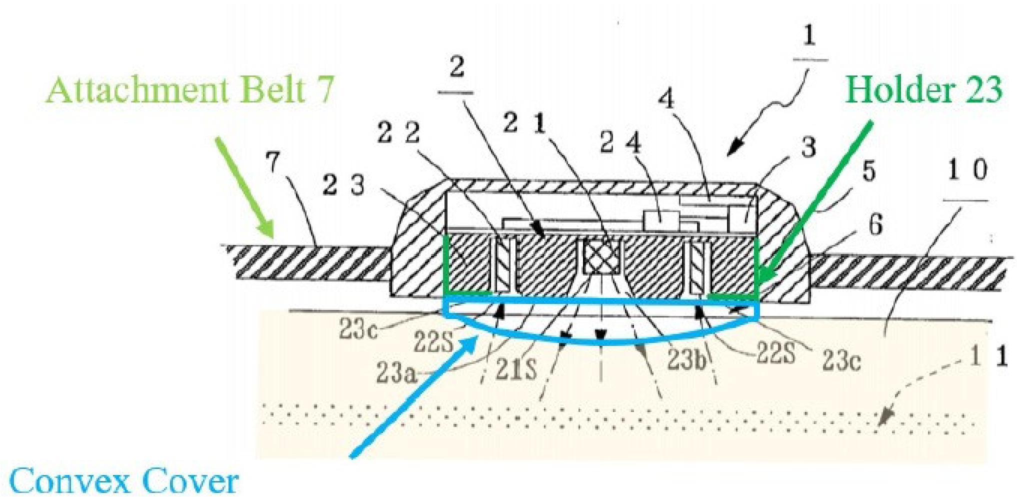
[1] Unless otherwise noted, emphases in quotations throughout my declaration are added.

12. Notably absent from Ohsaki's discussion of these benefits is any mention or suggestion that they relate to the shape of the perimeter of translucent board 8 (whether circular, rectangular, ovoid, or other). Rather, when describing the advantages associated with translucent board 8, Ohsaki contrasts a "convex detecting surface" from a "flat detecting surface," and explains that "if the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist," but that ***if the board "has a convex surface…variation of the amount of the reflected light…that reaches the light receiving element 7 is suppressed***." APPLE-1003, ¶78; APPLE-1014, [0015], [0025].

13. From this and related description, a POSITA would have understood that a protruding convex cover would reduce the adverse effects of user movement on signals obtainable by photodetectors which are positioned to detect light reflected from user tissue. APPLE-1003, ¶¶78-80; APPLE-1014, [0015], [0017], [0025], FIGS. 1, 2, 4A, 4B; *see also* APPLE-1006, [0012], [0013], [0023], [0024], [0026], [0030], [0034], FIGS. 1(a), 1(b). A POSITA would expect that these benefits would apply to the pulse wave sensor of Aizawa, as well as to other wearable physiological monitors.

14. In addition, as I explain with respect to the prior art figures reproduced below, the POSITA would have found it obvious to improve Aizawa's sensor based on Ohsaki's teachings, and would have been fully capable of making any inferences and creative steps necessary to achieve the benefits obtainable by modifying Aizawa's cover to feature a

convex detecting surface.[2] *See also* APPLE-1008, ¶¶14-15, FIG. 1. The following annotated FIG. 1(b) from Aizawa shows the results of the proposed combination:



APPLE-1006, FIG. 1(b)(annotated)

15. And, contrary to Masimo's contentions, the POSITA would have in no way been dissuaded from achieving those benefits by a specific body location associated with Ohsaki's sensor. POR, 33-39. Indeed, a POSITA would have understood that a light permeable convex cover would have provided improved adhesion as described by Ohsaki in a sensor placed, for example, on the palm side of the wrist or other locations on the body. APPLE-1014, [0025], Claim 3 (stating that "the detecting element is constructed to be worn on a user's wrist or a user's forearm" without specifying a back or front of the wrist or forearm), FIGS 4A, 4B; *see also* APPLE-1063, 91.

16. A POSITA would also have understood that certain locations present anatomical

[2] Nowhere in Ohsaki is the cover depicted or described as rectangular. APPLE-1014, [0001]-[0030]; FIGS. 1, 2, 3A, 3B, 4A, 4B.

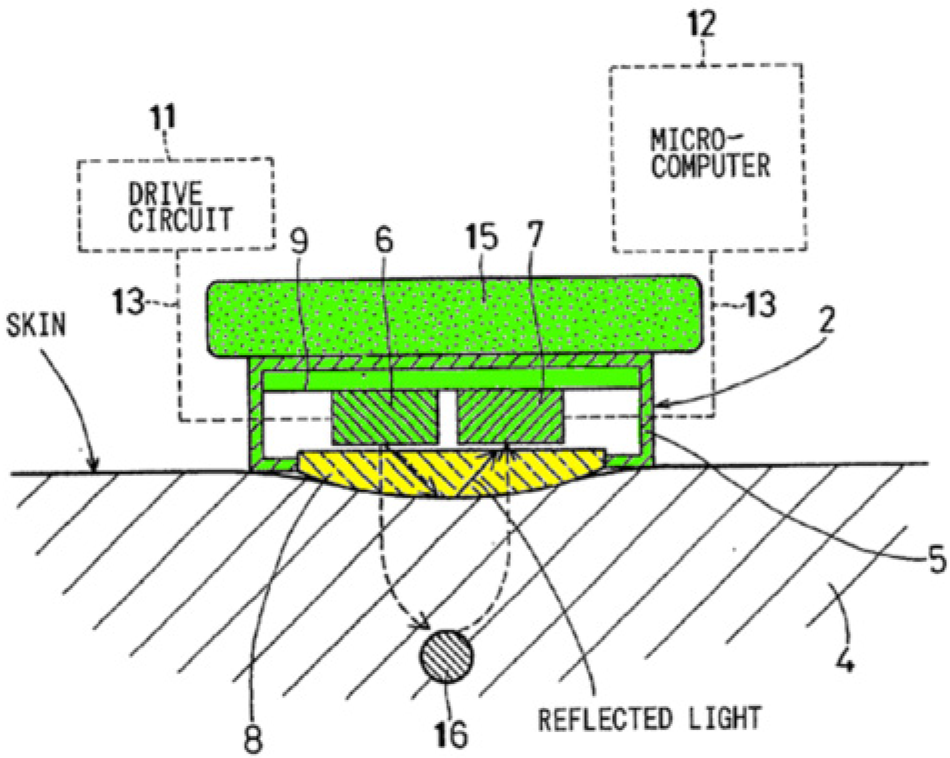
features that provide for easy measurement of large reflected light signals and other locations present anatomical features that reduce the amplitude of the reflected light signals. Because of this, a POSITA would be motivated to search for features from other references that can provide improved adhesion, improved light gathering, reduced leakage of light from external sources, and protection of the elements within the system in order to successfully detect a pulse wave signal from many locations.

17. For these and other reasons explained below, Masimo's arguments should be rejected. The sections below address the arguments with respect to Ground 1 presented in Masimo's POR and explain, in more detail, why those arguments fail.

A. Ohsaki does not teach or require that its translucent board 8 is "rectangular" in shape

18. In my first declaration, I explained that a POSITA would have modified Aizawa in view of Ohsaki such that Aizawa's cover "would include a convex surface, improving adhesion between a subject's wrist and a surface of the sensor." APPLE-1003, ¶¶76-82 (citing APPLE 1009, [0025] Ohsaki explains that the "convex surface of the translucent board 8" is responsible for this improved adhesion). Masimo argues that it is not the "convex surface" that improves adhesion in Ohsaki, but instead the "longitudinal shape" of "Ohsaki's translucent board [8]." *See* POR, 12, 24-30 (citing APPLE-1014, [0019]). However, the portion of Ohsaki cited does not include any reference to board 8. *See* APPLE-1014, [0019]. Ohsaki does ascribe a "longitudinal" shape to a different component: "detecting element 2." *See id*. Ohsaki never describes the "translucent board 8" as "longitudinal," and nowhere describes "translucent board 8" and "detecting element

2" as having the same shape. *See generally* APPLE-1014. In fact, as illustrated in Ohsaki's FIG. 2 (reproduced below), translucent board 8 (annotated yellow) is not coextensive with the entire tissue-facing side of detecting element 2 (annotated green).



APPLE-1014, FIG. 2 (annotated)

19. Based on the unsupported contention that translucent board 8 has a "very pronounced longitudinal directionality," Masimo concludes that the translucent board 8 has a "rectangular" shape that is allegedly incompatible with Aizawa. But Ohsaki never describes translucent board 8, or any other component, as "rectangular"; in fact, the words "rectangular" and "rectangle" do not appear in Ohsaki's disclosure. *See generally* APPLE-1014.

20. Indeed, the POR incorrectly assumes that because Ohsaki's light emitting element

and the light receiving element are arranged in a longitudinal structure, Ohsaki's translucent board must have a rectangular structure. APPLE-1014, [0009], [0019]; POR, 16-17. Yet a POSITA would have known and understood that an elliptical or circular sensor or board configuration can also have a longitudinal structure or appearance under a cross-sectional view. An example illustrating such an understanding, ***contrary to POR's flawed assumption***, is shown below in US Patent No. 6,198,951 ("Kosuda")'s FIGS. 3 and 4. APPLE-1010, 8:42-56.

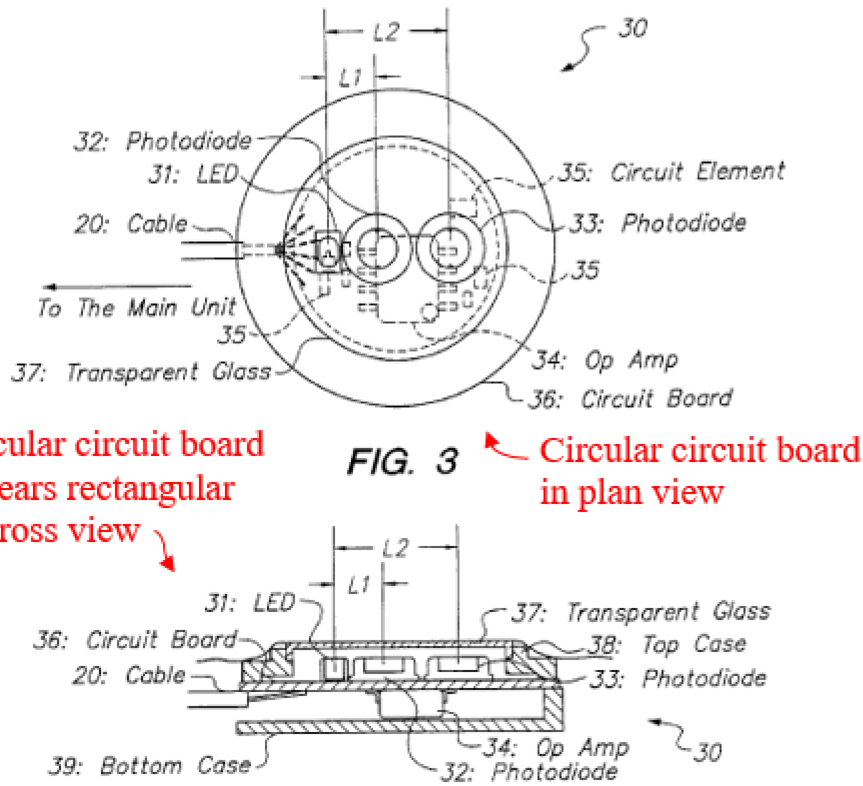


FIG. 4

APPLE-1010, FIGS 3 and 4

21. Attempting to confirm its false conclusion, Masimo asserts that "***Ohsaki illustrates two cross-sectional views*** of its board that confirm it is rectangular." POR, 16 (citing Ex. 2004, [36]-[39]). Masimo identifies these "two cross-sectional views" as FIGS. 1 and 2,

and infers the supposed "rectangular shape" of the translucent board 8 based on FIG. 1 showing the "short" side of the device, and FIG. 2 showing the "long" side of the same device. *See* POR, 16-18. But, according to Ohsaki, FIG. 2 is "a schematic diagram," not a cross-sectional view, and Ohsaki never specifies that FIGS. 1 and 2 are different views of the same device. APPLE-1014, [0013]. Accordingly, nothing in Ohsaki supports Masimo's inference that the "translucent board 8" ***must be*** "rectangular" in shape. *See, e.g.,* APPLE-1014, [0013], [0019], [0025], FIG. 2. Further, even if it is possible for the translucent board 8 to be "rectangular," Ohsaki certainly does not teach nor include any disclosure "***requiring***" this particular shape. *Id.*

22. The POR presents multiple arguments with respect to Ground 1 that are premised on Ohsaki ***requiring*** the translucent board 8 to be "rectangular." Because Ohsaki discloses no such shape for the translucent board 8, these arguments fail.

23. In addition, as discussed above, even if Ohsaki's translucent board 8 were somehow understood to be rectangular, a POSITA would have been fully capable of modifying Aizawa to feature a light permeable protruding convex cover to obtain the benefits attributed to such a cover by Ohsaki. For example, a POSITA would have found it obvious to include a circular light-permeable convex cover based on the teachings of Ohsaki, and take reasonable steps to make sure that the combination of a circular protruding convex cover would function with the other features present in Aizawa so as to provide the benefits discussed above.

B. A POSITA would have recognized the benefits of Ohsaki's teachings when applied to Aizawa's sensor

24. Masimo contends that "Ohsaki indicates that its sensor's convex board ***only*** improves adhesion when used on the ***back*** (i.e., watch) side of the wrist," and that "Aizawa ***requires*** its sensor be positioned on the palm side of the wrist," and therefore reaches a conclusion that "[a] POSITA seeking to improve adhesion of Aizawa's sensor would not incorporate a feature that only improves adhesion at a different and unsuitable measurement location." POR, 33. But Ohsaki does not describe that its sensor can ***only*** be used at a backside of the wrist, and Aizawa never requires that its sensor be positioned on the palm side of the wrist. Instead, at most, these disclosures simply describe these arrangements with respect to a preferred embodiment. APPLE-1014, [0019].

25. Indeed, Ohsaki's specification and claim language reinforce that Ohsaki's description would not have been understood as limited to one side of the wrist. For example, Ohsaki explains that "the detecting element 2…may be worn on the back side of the user's forearm" as one form of modification. *See* APPLE-1014, [0030], [0028] (providing a section titled "[m]odifications"). The gap between the ulna and radius bones at the forearm is even greater than the gap between bones at the wrist, which is already wide enough to easily accommodate a range of sensor sizes and shapes, including circular shapes. In addition, Ohsaki's claim 1 states that "the detecting element is constructed to be worn on a back side of a user's wrist ***or a user's forearm***." *See also* APPLE-1014, claims 1-2. As another example, Ohsaki's independent claim 5 and dependent claim 6 state that "the detecting element is constructed to be worn on a user's wrist or a user's forearm," ***without even mentioning a backside*** of the wrist or forearm. *See also* APPLE-1014,

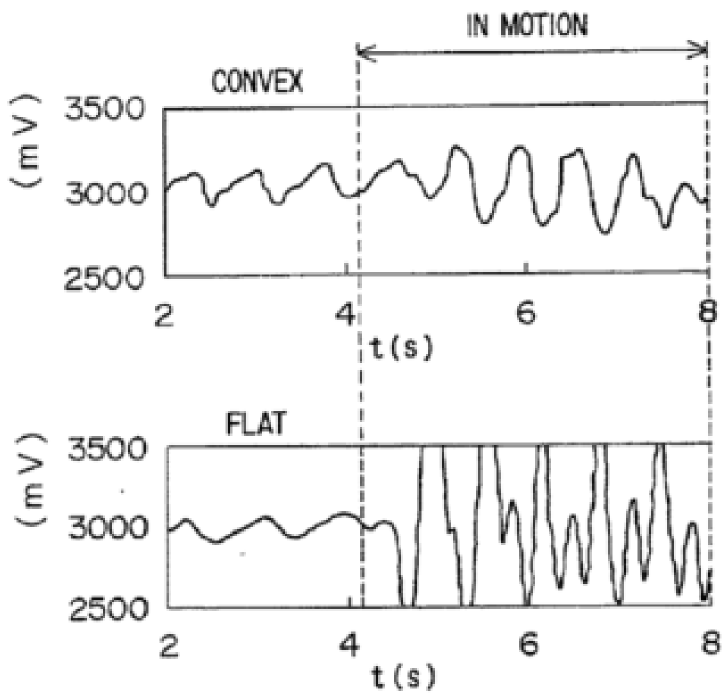
Claims 6-8. A POSITA would have understood this language to directly contradict Masimo's assertion that "[t]o obtain any benefit from Ohsaki's board, the sensor must be positioned on the backhand side of the wrist." POR, 23. A POSITA would have understood that Ohsaki's benefits provide improvements when the sensor is placed on either side of the user's wrist or forearm. APPLE-1014, [0025], FIGS. 4A, 4B. And while Masimo contends that Ohsaki teaches that a convex cover at the front (palm) side of the wrist somehow *increases* the tendency to slip, this is an argument that is nowhere supported by Ohsaki. For instance, paragraph 23 and FIGS. 3A-3B of Ohsaki that Masimo points to as allegedly providing support for this incorrect argument mentions nothing about the flat/convex nature of the cover and is instead merely demonstrating that pulse detection is generally less reliable when the user is in motion (and thus would benefit from changes such as adding a convex cover). APPLE-1014, [0024], FIGS. 4A, 4B.

26. POR presents several arguments with respect to Ground 1 that are premised on Ohsaki ***requiring*** the detecting element to be worn on a back side of a user's wrist or a user's forearm. Because Ohsaki requires no such location for the translucent board 8, these arguments fail.

27. Moreover, even assuming, for the sake of argument, that a POSITA would have understood Aizawa's sensor as being limited to placement on the backside of the wrist, and would have understood Ohsaki's sensor's "tendency to slip" when arranged on the front side as informing consideration of Ohsaki's teachings with respect to Aizawa, that ***would have further motivated*** the POSITA to implement a light permeable convex cover in

Aizawa's sensor, to improve detection efficiency of that sensor when placed on the palm side. APPLE-1014, [0015], [0017], [0023], [0025], FIGS. 1, 2, 3A, 3B, 4A, 4B.

28. When describing advantages associated with its translucent board, Ohsaki explains with reference to FIGS. 4A and 4B (reproduced below) that "if the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist," but that if the board "has a convex surface…variation of the amount of the reflected light…that reaches the light receiving element 7 is suppressed." APPLE-1003, ¶¶78-79; APPLE-1014, [0015], [0017], [0025].



APPLE-1014, FIGS. 4A, 4B

29. Contrary to Masimo's contentions, a POSITA would not have understood these benefits of a convex surface over a flat surface to be limited to one side or the other of the user's wrist, or to any particular location. APPLE-1014, [0023]-[0025]. Rather, a POSITA would have understood that, by promoting "intimate contact with the surface of the user's

skin," a light permeable convex cover would have increased adhesion and reduced slippage of Aizawa's sensor when placed on either side of a user's wrist or forearm, and additionally would have provided associated improvements in signal quality. APPLE-1014, [0015], [0017], [0025]; FIGS. 1, 2, 4A, 4B, claims 3-8; *see also* APPLE-1063, 87, 91. Indeed, a POSITA would have recognized that modifying Aizawa's flat plate to feature a convex protruding surface, as taught by Ohsaki, would have furthered Aizawa's stated goal of "improv[ing] adhesion between the sensor and the wrist" to "thereby further improve the detection efficiency." APPLE-1006, [0013], [0026], [0030], [0034].

30. Further, the POSITA would have been fully capable of employing inferences and creative steps when improving Aizawa based on Ohsaki's teachings, and would have expected success when applying those teachings. Indeed, a POSITA would have understood that adding a convex protrusion to Aizawa's flat plate would have provided an additional adhesive effect that would have reduced the tendency of that plate to slip. Among other things, it is well understood that physically extending into the tissue and displacing the tissue with a protrusion will provide an additional adhesive/gripping effect.

C. Modifying Aizawa's sensor to include a convex cover as taught by Ohsaki enhances the sensor's light-gathering ability

31. Masimo argues that the combined sensor "would direct light away from the detectors and thus decrease light collection and optical signal strength." *See, e.g.,* POR, 46-53. As explained below, a POSITA would have understood the opposite to be true—that a cover featuring a convex protrusion would improve Aizawa's signal-to-noise ratio by causing more light backscattered from tissue to strike Aizawa's photodetectors than would

have with a flat cover. APPLE-1063, 52, 86, 90; APPLE-1061, 84, 87-92, 135-141; APPLE-1017, 803-805; APPLE-1006, FIGS. 1(a)-1(b). The convex cover enhances the light-gathering ability of Aizawa's sensor.

32. Masimo and its witness, Dr. Madisetti, assert that "a POSITA would have believed that a convex surface would…direct[] light away from the periphery and towards the center of the sensor." In so doing, POR and Dr. Madisetti fail to articulate a coherent position—e.g., whether Masimo's position is that "all" light or only "some" light is directed "to" or "towards the center." POR, 24, 46-53, Ex. 2004, ¶¶86-97.

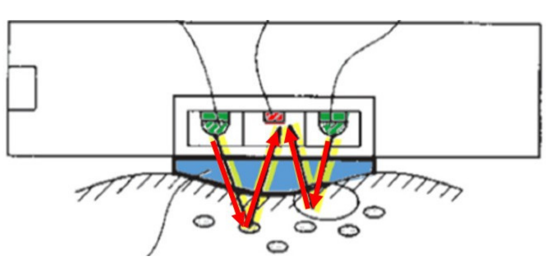
33. For example, Dr. Madisetti testified during deposition in one of the various related cases to this patent that "as I describe in my Declaration...if you have a convex surface...***all light*** reflected or otherwise would be condensed or directed towards the center." APPLE-1054, 40:4-11; *see also id.*, 127:22-128:18; Ex. 2004, ¶87 ("A POSITA Would Have Understood That a Convex Cover Directs Light ***To The Center*** Of The Sensor"). However, during the same deposition, Dr. Madisetti further stated that that a convex cover would redirect light "towards the center," which could be "a general area at which the convex surface would be redirecting…light" or "a point," while contrasting the phrase "to the center" from "towards the center." APPLE-1054, 105:12-107:1, 133:19-135:11.

34. In contrast, and as explained in more detail below, I have consistently testified that a POSITA would have understood that a convex cover improves "light concentration at pretty much ***all of the locations under the curvature of the lens***," and for at least that

reason would have been motivated to modify Aizawa's sensor to include a convex cover as taught by Ohsaki. Ex. 2006, 164:8-16.

i. Masimo ignores the well-known principle of reversibility

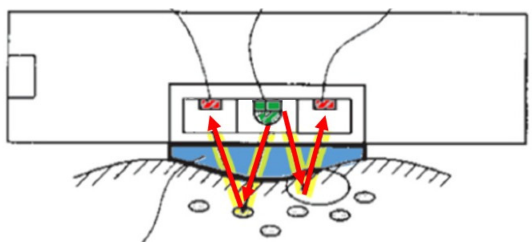
35. The well-known optical ***principle of reversibility*** dispels Masimo's claim that "a convex cover condenses light towards the center of the sensor and away from the periphery," when applied to Aizawa. POR, 46; APPLE-1061, 87-92; APPLE-1062, 106-111. According to the principle of reversibility, "a ray going from P to S will trace the same route as one from S to P." APPLE-1061, 92, 84; APPLE-1062, 101, 110; APPLE-1053, 80:20-82:20. Importantly, the principle dictates that rays that are not completely absorbed by user tissue will propagate in a reversible manner. In other words, every ray that completes a path through tissue from an LED to a detector would trace an identical path through that tissue in reverse, if the positions of the LED emitting the ray and the receiving detector were swapped. APPLE-1061, 92. To help explain, I have annotated Inokawa's FIG. 2 (presented below) to illustrate the principle of reversibility applied in the context of a reflective optical physiological monitor. As shown, Inokawa's FIG. 2, illustrates two example ray paths from surrounding LEDs (green) to a central detector (red):



APPLE-1008, FIG. 2 (annotated)

36. As a consequence of the principle of reversibility, a POSITA would have

understood that if the LED/detector configuration were swapped, as in Aizawa, the two example rays would travel identical paths in reverse, from a central LED (red) to surrounding detectors (green). A POSITA would have understood that, for these rays, any condensing/directing/focusing benefit achieved by Inokawa's cover (blue) under the original configuration would be identically achieved under the reversed configuration:



APPLE-1008, FIG. 2 (annotated)

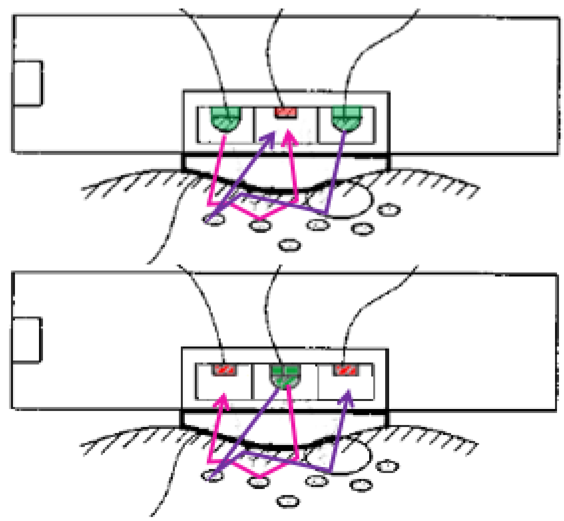
37. When factoring in additional scattering that may occur when light is reflected within human tissue, reversibility holds for each of the rays that are not completely absorbed; consequently, "if we're concerned with the impact of the lens on the system, it's absolutely reversible." APPLE-1059, 209:19-21, 207:9-209:21 ("one could look at any particular randomly scattered path…and the reversibility principle applies to all of the pieces [of that path] and, therefore, applies to the aggregate").

38. An example of reversibility in a situation with diffuse light, such as is present when LEDs illuminate tissue, is shown below from Hecht's Figure 4.12.

Figure 4.12 (a) Specular reflection. (b) Diffuse reflection. (Photos courtesy Donald Dunitz.)

39. In this figure 4.12a, collimated light is incident on a smooth surface, and exhibits specular reflection, in which parallel light rays encounter and are reflected from the surface and remain parallel. A POSITA would certainly understand specular reflection. In the case of the reflection as shown in Figure 4.12b, the random roughness of the surface scatters the incoming rays into many directions, and the resulting light would appear to be diffuse. However, even in this circumstance, the principle of reversibility applies–each individual ray can be reversed such that a ray travelling to the surface and scattered in a random direction can be followed backwards along exactly the same path.

40. In more detail, and as shown with respect to the example paths illustrated below (which include scattering within tissue), each of the countless photons travelling through the system must abide by Fermat's principle. APPLE-1062, 106-111. Consequently, even when accounting for various random redirections and partial absorptions, each photon traveling between a detector and an LED would take the quickest (and identical) path along the segments between each scattering event, even if the positions of the detector and LED were swapped.



41. To better understand the effect of a convex lens on the propagation of light rays towards or away from the different LEDs or detectors, the first and last segment of the light path may be representative of the light propagation of the various light rays. In the figures above, starting at the upper left, there is a pink-colored light ray emerging from the green LED and passing through the convex lens and entering the tissue. On the lower left, there is a pink-colored light ray leaving the tissue and entering the convex lens. As drawn, these rays are the same in position and orientation, except that the direction is exactly reversed. This illustration is consistent with the Principle of Reversibility as applied to this pair of possible light rays. According to the principle of reversibility, the upper light path from the LED to the first interaction with a corpuscle is exactly reversed. This same behavioral pattern applies to all of the segments of the many light paths that cross the interface at the surface of the convex lens. Importantly, in this example, the convex lens does not refract the incoming ray in a different direction from the outgoing ray, e.g., in a direction towards the center different from the outgoing ray. As required by the principle of reversibility, this incoming ray follows the same path as the outgoing ray, except in the reverse direction.

This statement is true for every segment of these light paths that crosses the interface between the tissue and the convex lens. Any ray of light that successfully traverses a path from the LED to the detector, that path already accounts for the random scattering as that scattering is what allowed the ray to go from the LED to a detector along the path to thereby be subsequently detected by the detector. A POSITA would have understood that the path is an aggregation of multiple segments and that the path is reversible as each of its segments would be reversible, consistent with Fermat's principle.

42. The statement about the reversibility of the segments of the light path which cross the interface between tissue and convex lens is consistent with the well-known and well-established Snell's law, which provides a simple algebraic relation between the angles of incidence and refraction as determined by the two indices of refraction. And Snell's law supports the basic understanding that the path of the light rays to/from a scattering event across the interface to/from the convex lens and on to/from the LED or photodetector must be reversible.

43. Based on this understanding of light rays and Snell's law, a POSITA would have understood that the positions of the emitters and detectors can be swapped in the proposed combination, and that the light paths from the initial situation would be reversed in the altered situation.

44. When confronted with this basic principle of reversibility during deposition, Dr. Madisetti refused to acknowledge it, even going so far as to express ignorance of "Fermat's principle, ***whatever that is***." APPLE-1054, 89:12-19. Yet Fermat's principle, which states

that a path taken by a light ray between two points is one that can be traveled in the least time, regardless of the direction of travel, is one of the most fundamental concepts in optics/physics and plainly requires the basic principle of reversibility. APPLE-1061, 87-92; APPLE-1062, 106-111. This is in no way a new theory, as this core concept dates back many years, and is offered in Aizawa itself. Indeed, ***Aizawa recognizes this reversibility***, stating that while the configurations depicted include a central emitter surrounded by detectors, the "same effect can be obtained when…a plurality of light emitting diodes 21 are disposed around the photodetector 22." APPLE-1006, [0033]; APPLE-1059, 209:19-21.

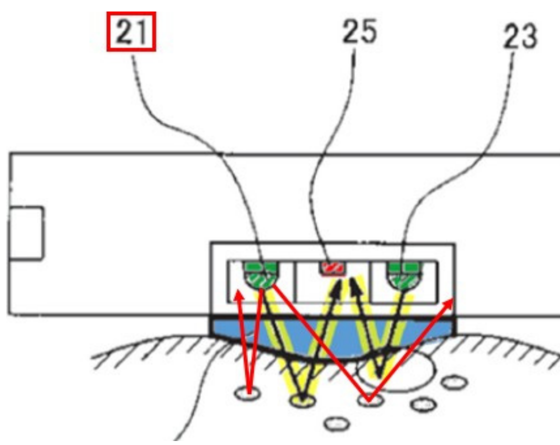
45. In short, based at least on the principle of reversibility, a POSITA would have understood that both configurations of LEDs and detectors—*i.e.*, with the LED at the center as in Aizawa or with the detector at the center as in Inokawa—would identically benefit from the enhanced light-gathering ability of a convex lens/protrusion.

ii. Masimo ignores the behavior of scattered light in a reflectance-type pulse sensor

46. Because Aizawa is a reflectance-type pulse sensor that receives diffuse, backscattered light from the measurement site, its cover/lens cannot focus all incoming light toward the sensor's center. Ex. 2006, 163:12-164:2 ("A lens in general…doesn't produce a single focal point"). Indeed, reflectance-type sensors work by detecting light that has been "partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector." APPLE-1063, 86. A POSITA would have understood that light which backscatters from the measurement site after diffusing

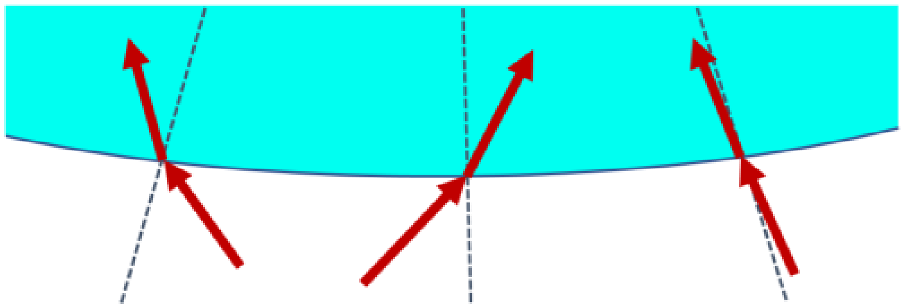
through tissue reaches the active detection area from various random directions and angles. APPLE-1056, 803; APPLE-1063, 90, 52.

47. As noted above, basic law of refraction, namely Snell's law, dictates this behavior of light. APPLE-1061, 84; APPLE-1062, 101; APPLE-1053, 80:20-82:20; APPLE-1063, 52, 86, 90. For example, referring to Masimo's version of Inokawa's FIG. 2, further annotated below to show additional rays of light emitted from LED 21, it is clearly seen how some of the reflected/scattered light from the measurement site does not reach Inokawa's centrally located detector:



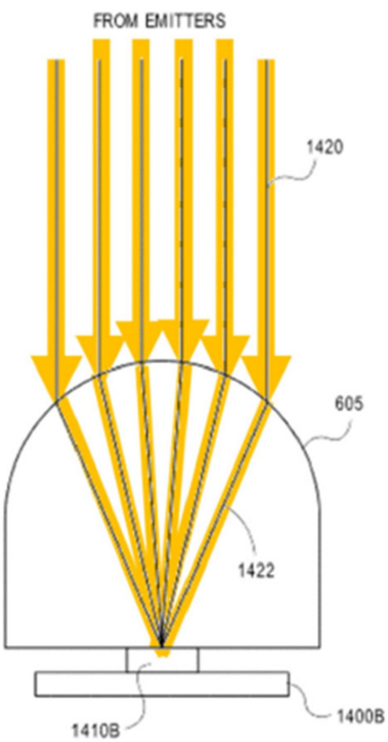
APPLE-1008, FIG. 2 (annotated); POR, 11.

48. For these and countless other rays that are not shown, there is simply no way for a cover to focus all light at the center of the sensor device. APPLE-1061, 84; APPLE-1062, 101; APPLE-1053, 80:20-82:20. The illustration I provide below shows how Snell's law determines a direction of a backscattered ray within a convex cover, thus providing a stark contrast to Masimo's assertions that all such rays must be redirected to or towards the center:



49. Indeed, far from focusing light to the center as Masimo contends, Ohsaki's convex cover provides a slight refracting effect, such that light rays that may have otherwise missed the detection area are instead directed toward that area as they pass through the interface provided by the cover. This is particularly true in configurations like Aizawa's in which light detectors are arranged symmetrically about a central light source, so as to enable backscattered light to be detected within a circular active detection area surrounding that source. APPLE-1063, 86, 90. The slight refracting effect is a consequence of the similar indices of refraction between human tissue and a typical cover material (e.g., acrylic). APPLE-1057, 1486; APPLE-1058, 1484).

50. To support the misguided notion that a convex cover focuses all incoming light at the center, Masimo relies heavily on the '366 patent's FIG. 14B (reproduced below):



APPLE-1001, FIG. 14B (as annotated at POR, 48)

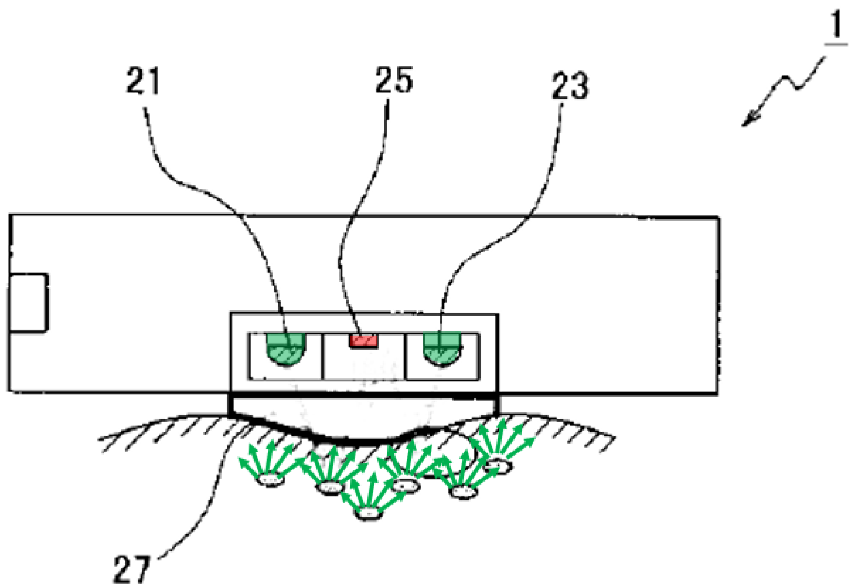
51. Masimo and Dr. Madisetti treat this figure as an illustration of the behavior of all convex surfaces with respect to all types of light, and conclude that "a convex surface condenses light away from the periphery and towards the sensor's center." POR, 47-48; APPLE-1054 ("…a POSA viewing [FIG. 14B]…would understand that light, ***all light***, light from the measurement site is being focused towards the center").

52. But the incoming collimated light shown in FIG. 14B is not an accurate representation of light that has been reflected from a tissue measurement site. The light rays (1420) shown in FIG. 14B are collimated (i.e., travelling paths parallel to one another), and each light ray's path is perpendicular to the detecting surface.

53. By contrast, the detector(s) of reflectance type pulse detectors detect light that has been "partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector." APPLE-1063, 86. For example, a POSITA would have understood from Aizawa's FIG. 1(a) that light that backscatters from the measurement site after diffusing through tissue reaches the circular active detection area provided by Aizawa's detectors from various random directions and angles, as opposed to all light entering from the same direction and at the same angle as shown above in FIG. 14B. APPLE-1063, 52, 86, 90; APPLE-1017, 803-805; *see also* APPLE-1012, FIG. 7. Even for the collimated light shown in FIG. 14B, the focusing of light at the center only occurs if the light beam also happens to be perfectly aligned with the axis of symmetry of the lens. If for example, collimated light were to enter the FIG. 14B lens at any other angle, the light would focus at a different location in the focal plane. Further, if the light were not collimated, so that rays enter the lens with a very wide range of incident angles, there would be no focus at all, and many rays will be deflected away from the center. Moreover, since "the center" takes up a very small portion of the total area under the lens, the majority of rays associated with diffuse light entering the lens would arrive at locations away from the center.

54. The light rays from a diffuse light source, such as the LED-illuminated tissue near a pulse wave sensor or a pulse oximeter, include a very wide range of angles and directions, and cannot be focused to a single point/area with optical

elements such as lenses and more general convex surfaces. The example figure below illustrates light rays backscattered by tissue toward a convex lens; as consequence of this backscattering, a POSITA would have understood that the backscattered light will encounter the interface provided by the convex board/lens at all locations from a wide range of angles. This pattern of incoming light cannot be focused by a convex lens towards any single location.



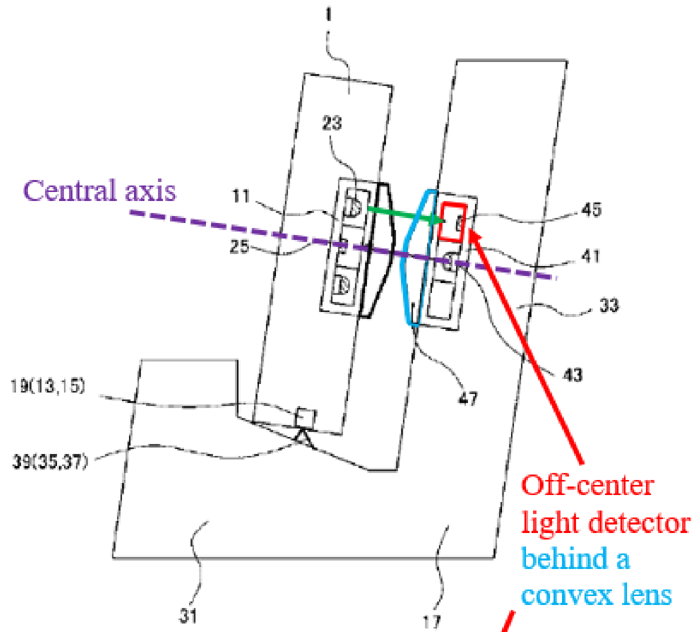
APPLE-1061, 141 (annotated)

55. To the extent Masimo contends that only *some* light is directed "towards the center" and away from Aizawa's detectors in a way that discourages combination, such arguments also fail. Indeed, far from *focusing* light to a single central point, a POSITA would have understood that Ohsaki's cover provides a slight refracting effect, such that light rays that may have missed the active detection area are instead directed toward that area as they pass through the interface provided by the lens. APPLE-1063, 52; APPLE-1007, [0015]; APPLE-

1061, 87-92, 135-141; APPLE-1054, 60:7-61:6, 70:8-18.

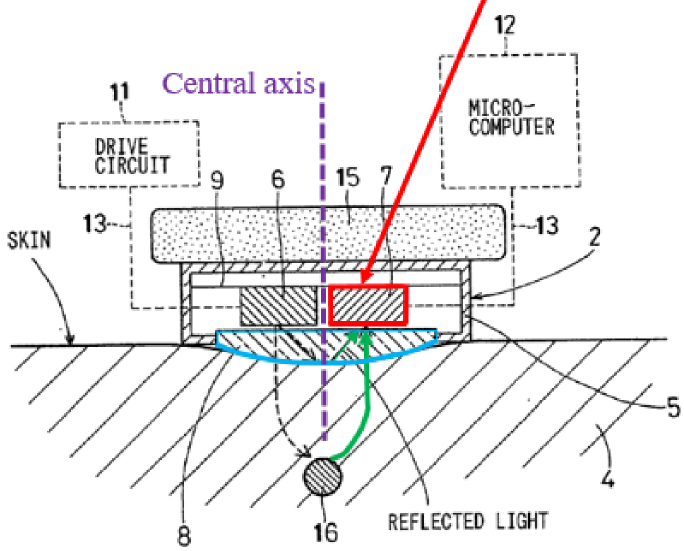
56. Masimo's technically and factually flawed argument is exposed by multiple prior art references, including the Ohsaki and Inokawa references which are the key elements of our combinations. As shown in the figures below, Ohsaki and Inokawa both show embodiments which use a convex lens to direct light to detectors that are not located at the center of a sensor. APPLE-1014, FIG. 2; APPLE-1008, FIG. 3. In Inokawa's Figure 2, an off-center emitter and sensor are configured to send and receive text messages, and are capable of success, even though the detector is not positioned at the center.

(FIG. 3)



APPLE-1008, FIG. 3

FIG. 2

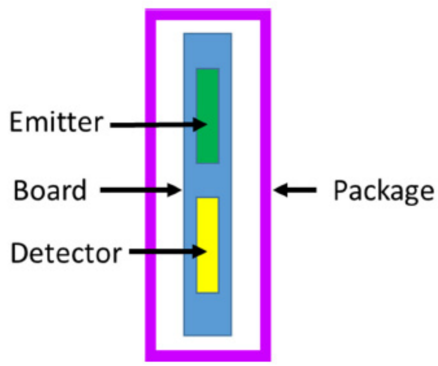


APPLE-1014, FIG. 2

57. If, as asserted by the Patent Owner, a convex lens is required to condense, direct, or focus the light to the center, the embodiments disclosed by Ohsaki and Inokawa would all fail because there is no detector at the center to detect all of the light that would be directed towards the center by the convex board. The

Ohsaki and Inokawa embodiments (reproduced above) do not show or otherwise teach that its convex board directs all light towards the center.

58. Moreover, even in Patent Owner and Dr. Madisetti's illustration (shown below), which represents their understanding of Ohsaki's FIGS. 1 and 2, the detector is not located in the center. Ex. 2004, ¶38. If Patent Owner and Dr. Madisetti's arguments were correct (which they are not), Ohsaki embodiments in FIGS. 1 and 2 would fail to produce a functioning pulse wave sensor—which is not the case—and Patent Owner has never claimed the same either.



Ex. 2004, ¶38

59. For all of these reasons, including details from the interpretation of Ohsaki's embodiment provided by Dr., Madisetti and the Patent Owner, it would have been obvious to a POSITA that a convex cover would have been successfully used with a sensor design with peripheral detectors (as in Aizawa and Ohsaki), and that it would be reasonable to expect the benefits of improved adhesion as explained above and in my previous declaration.

D. A POSITA would have been motivated to select a convex cover to protect the optical elements

60. Masimo contends that "a POSITA would have understood that Aizawa's flat plate would provide better protection than a convex surface" and be "less prone to scratches." POR, 53-54. Even assuming this to be true, one possible disadvantage that competes with the known advantages of applying Ohsaki's teachings to Aizawa's sensor would not have negated a POSITA's motivation to combine. Moreover, a POSITA would have understood the ***multiple*** advantages of a convex cover described in my earlier declaration outweigh any alleged possibility of scratching (which, at any rate, has nothing whatsoever to do with the protection of optical elements within Aizawa's sensor). Moreover, by choosing a suitable material of the protrusion to be scratch-resistant, such as glass, it would have been obvious for a POSITA to achieve both benefits (light gathering and scratch-resistance) at once.

E. Patent Owner mischaracterizes Aizawa's principle of operation

61. Masimo appears to be arguing that Aizawa's photodetectors cannot be connected in parallel because Aizawa seeks to "help address sensor dislocation" and that this function, for some reason, cannot be maintained if its detectors were connected in parallel. POR, 54-58. As I explain in more detail below, this argument from Patent Owner either completely misunderstands and/or mischaracterizes Aizawa's actual teachings.

62. As I mentioned during my deposition, a POSITA would have recognized and/or found it obvious that the photodetectors of Aizawa are connected in

parallel. Ex. 2026, 72:3-9. This is because a POSITA would have known that connecting multiple photodetectors together in parallel allows the current generated by the multiple photodetectors to be added to one another, which would subsequently ensure that even if one of multiple sensors connected in parallel were to be displaced so as to receive no signal, the fact that all the sensors are connected in parallel such that their signals are summed means that a signal will still be detected, in accordance with Aizawa's objective. As explained by Aizawa, the pulse rate is determined by computing the number of outputs above the threshold value per unit time (Aizawa paragraph 28), which is consistent with how a POSITA would consider analyzing the output based on summing of the sensor currents. I explained this previously in my first declaration. APPLE-1003, ¶¶102-103. Thus, to the extent Aizawa itself doesn't expressly teach connecting its photodetectors in parallel, this is merely an implementation detail that a POSITA would have been well aware of (and in fact performed very commonly). *See* APPLE-1024, 3017; APPLE-1025, 4:23-30. Patent Owner seems to be of the view that FIG. 3 of Aizawa somehow supports their false assertion that Aizawa's sensors cannot be connected in parallel; however, FIG. 3 is merely a "schematic diagram" that is provided to illustrate what a waveform looks like. Indeed, there is no disclosure anywhere in Aizawa to suggest that it is even capable of somehow monitoring the signals of each photodetector, and there is certainly no need to do so if its sensors are connected in parallel. APPLE-1006, [0019],

[0028], FIG. 1(b). Instead of attributing the ability to account for sensor displacement to individually connected/monitored photodetectors, as Masimo appears to contend, Aizawa actually explains that the ability to account for sensor displacement comes from, among other things, disposing its photodetectors "around the light emitting diode and not linearly" and by "expand[ing]...the light receiving area." APPLE-1006, [0009], [0012]. Not surprisingly, these are precisely some of the benefits provided by the Aizawa combination as set forth.

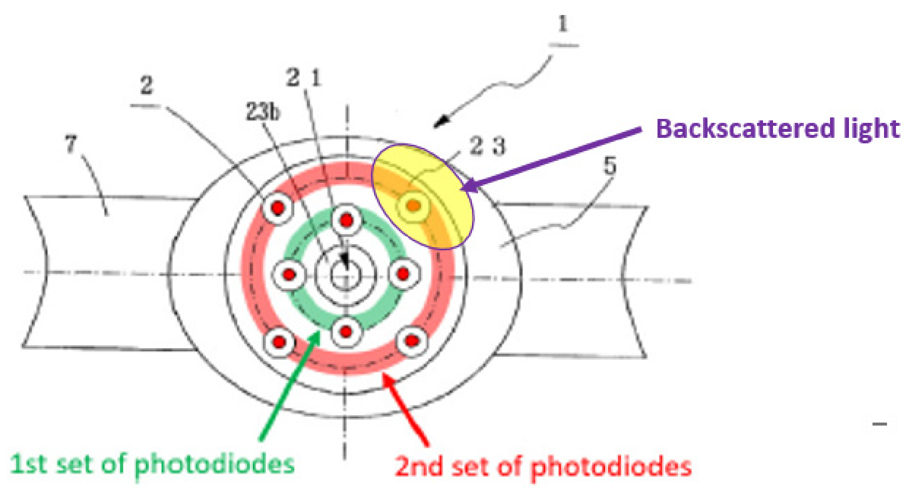
63. Thus, connecting Aizawa's photodetectors in parallel allows Aizawa to account for sensor displacement, instead of preventing it as Masimo alleges, since the signals from all the detectors will be included in the output, thereby allowing the system to account for any one detector that may not be receiving a signal due to displacement.

F. A POSITA would have been motivated to add a second ring of sensors to Aizawa

64. I previously explained at length why a POSITA would have been motivated to add a second ring of sensors to Aizawa, most notably to allow the modified system to "collect a bigger portion of backscattered light intensity." APPLE-1003, ¶¶ 56, 70, 75, 107-109. Yet inexplicably, Masimo argues that "Petitioner gives no plausible reason why a POSITA would have been motivated to modify Aizawa to add an entire second ring of four detectors farther from the emitter...." POR, 59; *see also* POR, 61 ("Petitioner never explains why, given these straightforward options to increase signal strength, a POSITA would instead

add an entire new circle of detectors farther from the emitter....").

65. But as I previously explained, adding a second ring of sensors to Aizawa allows the modified Aizawa system to "widen[] the active area of the PD" and consequently "collect a bigger portion of backscattered light intensity." APPLE-1003, ¶¶56-70; APPLE-1024, 3019. To illustrate, as shown below, a measurement scenario where the backscattered light only reaches the area highlighted in yellow would not result in light detection without the presence of additional sensors provided by the second ring:



APPLE-1006, FIG. 1(a)

66. Like I said during my deposition, "having a larger detector area is beneficial" because this would "fill up more of the space, that would give you the opportunity to capture more light reflected back from the tissue." Ex. 2026, 102:5-104:4.

67. Additionally, contrary to Masimo's arguments, adding a second ring of detectors would not have led to an undesirable increase in power consumption.

POR, 58-61. Among other things, the LEDs, not the photodetectors, are responsible for consuming the dominant power in the system. Ex. 2026, 104:5-105:14. Thus, widening the detection area to collect a bigger portion of backscattered light, as would be the case with the modified Aizawa system with two rings of detectors, would result in improved light collection efficiency by allowing additional light to be captured and thereby allowing a lower brightness of LEDs to be used, which would result in reduced power consumption. APPLE-1003, ¶¶69-71.

68. Even assuming for the sake of argument that power consumption is increased through this modification, which for reasons I explained above it would not, a POSITA nevertheless would have been capable of weighing potential tradeoffs, for instance increased power consumption vs. collection of more of the backscattered light than would be possible if detector placement was limited to only one ring. Such design choices are routinely made by a POSITA in consideration of the overall design/engineering objectives.

G. A POSITA would have been motivated to keep the first and second rings of detectors separate

69. Not able to dismiss the clear benefits that Mendelson-2003's two-ring design would provide to Aizawa, Masimo further tries to dismiss such teachings as being for "performing experiments." POR, 61. Masimo argues that "even if a POSITA would have added a second ring of detectors, Mendelson 2003 evidences that a POSITA would not have kept the first and second ring of

detectors separate or separately amplified the aggregated signals." POR, 65. They appear to be arguing that Mendelson-2003 requires a single large photodetector that covers the same area covered by the two rings of detectors.

70. But Mendelson-2003 does not say that using a single, large detector is somehow superior to using multiple, smaller detectors. Instead, the main premise behind Mendelson-2003 is that the two situations are equivalent; that is why they are able to use one configuration (*e.g.,* two rings of detectors) in place of the other (*e.g.,* single large detector). Thus, a POSITA, looking to implement the teachings of Mendelson-2003 regarding the benefits of expanding the detection area, would have recognized that one way to achieve the same would be through the precise configuration as taught by Mendelson-2003, namely using two rings of discrete photodetectors that are each connected in parallel and that each provide a separate stream. Indeed, it is well known that a single larger photodetector can be replaced with multiple smaller ones. *See, e.g.,* APPLE-1016, 915 ("[W]e showed that a concentric array of ***either discrete PDs, or an annularly-shaped PD ring***, could be used to increase the amount of backscattered light detected..."). Thus, a POSITA trying to maximize the detection area to increase sensitivity and lower power consumption, as in Mendelson-2003, would have recognized that one way to implement this configuration is to, like Mendelson-2003, use two rings of parallel detectors.

71. Lastly, as I previously described in my first declaration, keeping the two

signal streams separate provides multiple other benefits, such as detecting sensor displacement as well as being able to more reliably detect weak signals that are only picked up by the outer ring, for example, by utilizing different gain in the amplification of signals captured by the outer ring. *See* APPLE-1003, ¶¶104-106. Masimo's arguments that the benefits of maintaining separate streams as per Mendelson '799 in order to detect dislocation is inapplicable to the modified Aizawa system is misplaced because a POSITA would have recognized that Mendelson '799's general teachings regarding the comparison of "near" and "far" detectors in order to sense dislocation is more broadly applicable to the "near" and "far" rings in Aizawa-Mendelson-2003. APPLE-1025, 12:62-13:5, 13:19-30; APPLE-1003, ¶104. Moreover, Masimo's arguments that "the weaker signals at the outer ring are precisely why a POSITA would have used Aizawa's existing single ring embodiment" entirely misses the point that expanding the detection area by use of additional rings gives the system an opportunity to pick up weaker signals that otherwise would have been missed completely. POR, 65.

III. Ground 2 Establishes Obviousness

72. Masimo argues that Ground 2 should be rejected for the same reasons as Ground 1. As explained above, Ground 1 establishes obviousness of the claimed features, thus these grounds additionally render the claims obvious. Moreover, I note that nothing in Ohsaki links the benefits of its convex cover to the use of any particular type of strap.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.

Petitioner,

v.

MASIMO CORPORATION,

Patent Owner.

Case IPR2020-01737
U.S. Patent 10,709,366

DECLARATION OF VIJAY K. MADISETTI, PH.D.

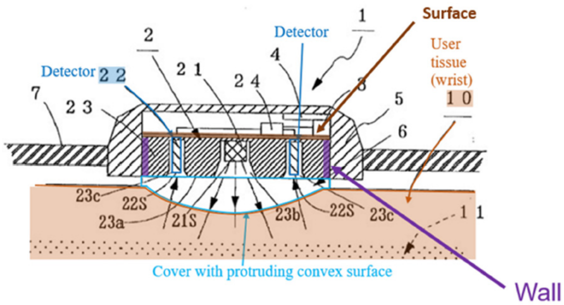
Masimo Ex. 2004
Apple v. Masimo
IPR2020-01737

benefit from Ohsaki's rectangular board, the sensor must be position on the backhand side of the wrist, which is far from the radial and ulnar arteries that are found on the palm side of the wrist, where Aizawa's sensor takes its pulse measurements. Finally, a POSITA would have believed that adding a convex-shaped cover to Aizawa's sensor would have a detrimental optical impact by directing light away from Aizawa's peripherally located detectors, resulting in reduced signal strength and decreased detection efficiency. Further a POSTIA would not have selected a convex shape for protecting Aizawa's sensor components because of the complications and problems associated with adding a convex surface to Aizawa's flat plate.

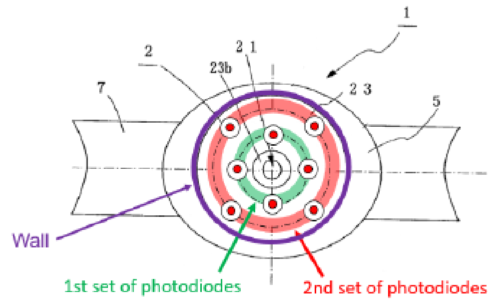
1. A POSITA Would Have Understood That Ohsaki's Rectangular Board Would Not Work With Aizawa's Circular Sensor Arrangement

a) Modifying Ohsaki's Rectangular Board Would Eliminate The Limited Advantage Of Reduced Slipping Taught By Ohsaki

53. Dr. Kenny's combination changes Ohsaki's structure and eliminates the longitudinal shape that gives Ohsaki's rectangular board the ability to fit within the user's anatomy and prevent slipping. Ex. 1003 ¶79; Ex. 1014 ¶[0019]. Dr. Kenny's illustrated combination changes Ohsaki's rectangular board (discussed in Sections VII.A.1-2, above) and makes it circular so that it can cover Aizawa's holder 23 (which Dr. Kenny outlined in purple in the figure below):



Dr. Kenny's illustration of the combination of Ohsaki, Aizawa, Mendelson 2003, and Goldsmith (Ex. 1003 ¶114)

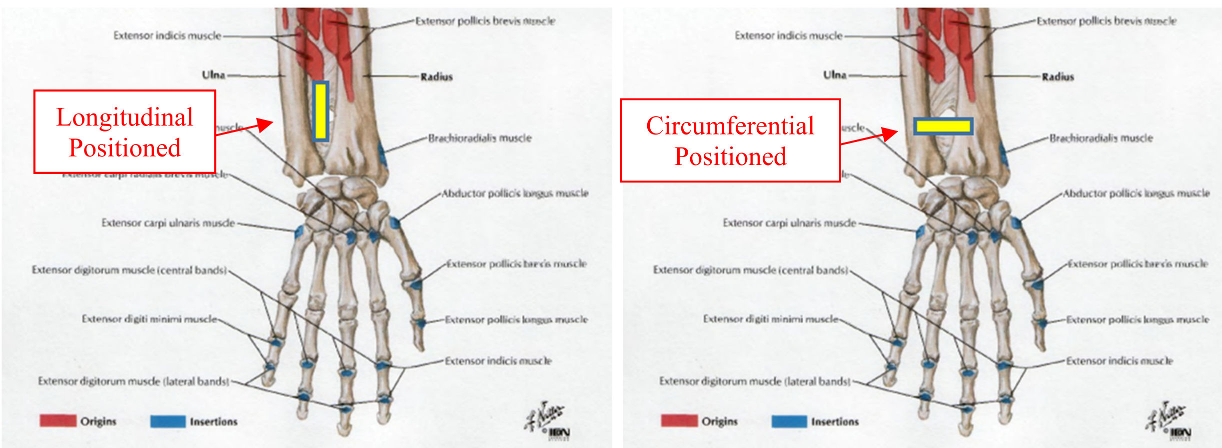


Dr. Kenny's illustration of Aizawa's modified circular sensor (Ex. 1003 ¶112)

54. Dr. Kenny asserts that a POSITA would have been motivated to add Ohsaki's rectangular board to Aizawa's circular sensor to improve adhesion. Ex. 1003 ¶79; *see also, e.g.*, ¶¶76, 80. As an initial point, Ohsaki does not specifically discuss improving adhesion, and instead refers to a particular configuration that prevents slipping and various other configurations that have a tendency to slip. Ex. 1014 ¶¶[0006], [0010], [0019], [0023], [0025]. Dr. Kenny equates Ohaski's disclosure of a convex surface that prevents slippage with "improv[ing] adhesion." Ex. 1003 ¶79 (citing Ex. 1014 ¶[0025]). But Dr. Kenny's proposed modification eliminates the longitudinal shape that Ohsaki identifies as an important part of reducing slipping. Ex. 1014 ¶[0019].

55. Ohsaki places its linear, longitudinal sensor on the backhand side of a user's wrist to avoid interacting with bones in the wrist. *See* Ex. 1014 ¶¶[0006] (discussing need to avoid pressing on "two bones (the radius and the ulna)"), [0024] ("the radius and the ulna inside the user's wrist 4 are not pressed"); *see*

also, *e.g.*, ¶¶[0023]-[0024], Abstract, Title, Fig. 1 (Ohsaki device worn on back side of wrist). As illustrated below (left), the forearm bones (the radius and ulna) on the arm's backhand (or watch) side create a longitudinal opening at the junction between the wrist and forearm with no muscle insertions. Ex. 2010 at 49 (Plate 434). The radius and ulna, against which Ohsaki warns against pressing (Ex. 1014 ¶¶[0006], [0024]), are on either side of this longitudinal opening.



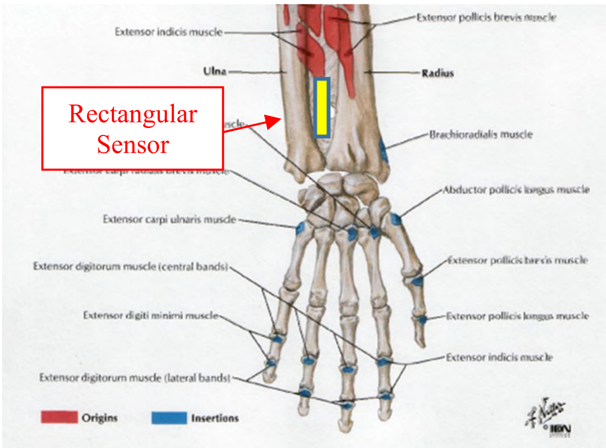
Anatomical drawing of the back side (posterior) of the hand, wrist, and forearm (partial view from Ex. 2010 at 49 (Plate 434))
Left: Conceptual view of how a rectangular sensor that is positioned in longitudinal direction on the wrist/forearm can avoid the radius and ulna
Right: Conceptual view of how the same rectangular sensor placed in the circumferential direction on wrist/forearm interacts with the radius and ulna

56. Ohsaki indicates that its sensor's longitudinal direction needs to be aligned with the longitudinal direction of the longitudinal opening of the user's arm to prevent slipping. Ex. 1014 ¶[0019]. If the sensor's longitudinal direction is aligned with the circumferential direction of the user's wrist, the undesirable result is "a tendency [for Ohsaki's sensor] to slip off." Ex. 1014 ¶[0019]. As

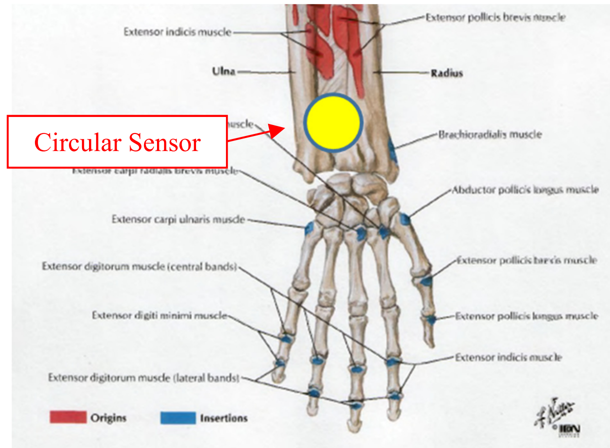
illustrated above (right), a rectangular structure like Ohsaki's sensor and board that is aligned with the circumferential direction of the user's wrist undesirably interacts with the radius and ulna, which Osaki warns against. Ex. 1014 ¶¶[0006], [0024]. In contrast, a rectangular structure aligned with the longitudinal direction of the user's wrist can avoid pressing against the radius and ulna.

57. Thus, a POSITA would have understood that changing the shape of Ohsaki's rectangular board to circular would not preserve its ability to prevent slipping. Instead, if Ohsaki's rectangular board were changed into a circular shape, a POSITA would have believed it would have resulted in slipping, and thus eliminated the advantage of Ohsaki's board. This is because a circular shape extends equally in all directions, including in the circumferential direction of the user's wrist, which Ohsaki explains results in slipping. Ex. 1014 ¶[0019]. As a result, a circular shape cannot be placed in a longitudinal direction and thus cannot align with the longitudinal direction of the user's wrist, as taught by Ohsaki. As illustrated below, unlike a longitudinal sensor, a symmetrical circular shape (with a diameter equal to the long side of the rectangle, below left) would not fit within the user's anatomy in a way that it could avoid undesirably pressing against the user's radius and ulna, which Ohsaki cautioned against.

Ohsaki's Longitudinal Teachings



Dr. Kenny's Proposed Combination



Anatomical drawing of the back side (posterior) of the hand, wrist, and forearm (partial view from Ex. 2010 at 49 (Plate 434))
Left: Conceptual view of how a rectangular sensor that is positioned in longitudinal direction on the wrist/forearm can avoid the radius and ulna
Right: Conceptual view of how a circular sensor with the same diameter as the length of the rectangular board interacts with the radius and ulna

58. Because a symmetrical circular shape will press on the user's arm in all directions, it will interact with the user's bone structure. Ohsaki teaches that such interactions with the user's anatomy are undesirable and result in slipping. Ex. 1014 ¶¶[0006], [0023]-[0024].

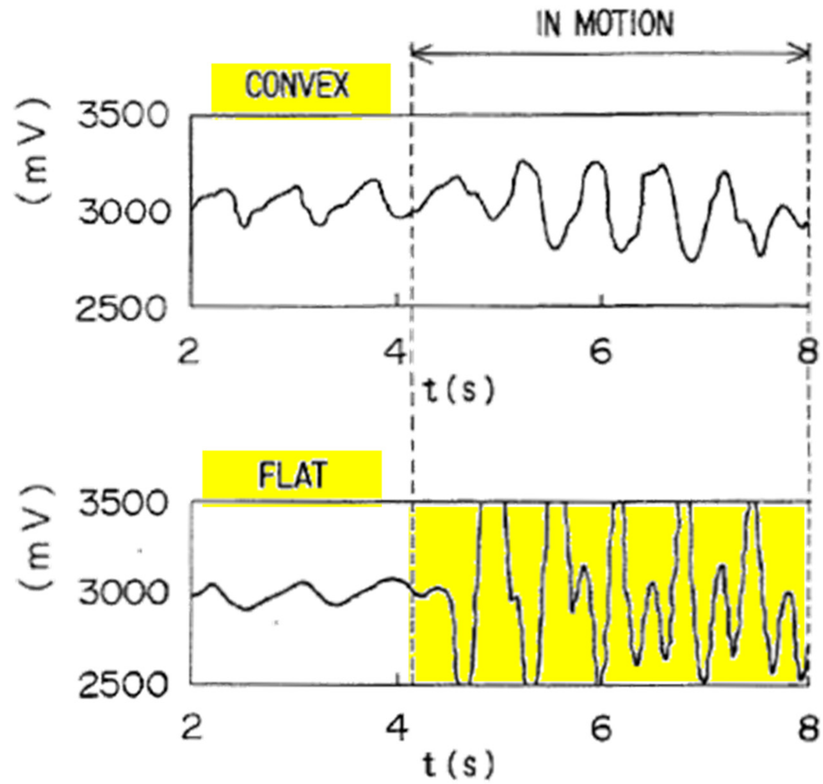
59. Dr. Kenny did not discuss Ohsaki's disclosure that when Ohsaki's rectangular sensor was placed in one orientation (up-and-down the arm), it helped prevent slipping. Ex. 1014 ¶[0019]. Dr. Kenny also did not discuss Ohsaki's explanation that rotating the sensor 90 degrees, such that the long direction points in the circumferential direction of the user's wrist, the sensor "has a tendency to slip." Ex. 1014 ¶[0019]; *see* Ex. 1003 ¶¶58-59, 76-84.

identified by Ohsaki corresponds to the irregular pattern shown in Figure 3B, compared to the pattern of measurements from the back side of the wrist shown in Figure 3A. For measurements using a convex board on the back side of the wrist, Ohsaki explains Figure 3A shows "the pulse wave is detected stably without being affected by the movement of the user's wrist...." Ex. 1014 ¶[0024].

79. Dr. Kenny does not cite or discuss Ohsaki's Figures 3A-3B when discussing the motivation for modifying Aizawa's palm-side sensor with a lens/protrusion similar to Ohsaki's board. Ex. 1003 ¶¶76-84; *see also* ¶¶114-115. Instead, Dr. Kenny discusses Ohsaki's Figures 4A-4B, which compares measurements using a sensor with a convex surface or a flat surface on the back (i.e., watch) side of the wrist. Ex. 1003 ¶¶77-78.

FIG. 4A

FIG. 4B



Ohsaki Figs. 4A-4B comparing convex and flat surfaces
for measurements taken from the back side of the wrist (color added)

80. Ohsaki states that Figure 4B shows that when measurements taken from the back side of the wrist using a sensor with a *flat* surface, "the detected pulse wave is adversely affected by the movement of the user's wrist." Ex. 1014 ¶[0025]. Ohsaki also indicates that a board with a *convex* surface prevents "slip[ping] off the detecting position" on the back side of the wrist, as shown in Figure 4A. Ex. 1014 ¶[0025]; *see also* ¶¶[0023]-[0024] (comparing tendency to slip on front and back side of wrist). Figure 4A, which illustrates Ohsaki's convex sensor placed on the back side of the wrist, contrasts with the measurements shown in Figure 3B (which illustrates a convex surface slips on the palm side of

the wrist). Figure 4A is consistent with Figure 3A (which illustrates a convex surface has comparatively less motion signal on the back side of the wrist). Taken together, A POSITA would have understood that Ohsaki's convex surface may prevent slipping on the back side of the wrist, if it is positioned appropriately (e.g., in the correct orientation with the long side up-and-down the wrist). Ex. 1014 ¶¶[0019], [0023]-[0025], Figs. 3A-3B, 4A-4B.

81. The rest of Ohsaki's disclosure recognizes the limitations on any benefit derived from its convex surface. Ohsaki repeatedly specifies that its sensor "is worn on the back side of a user's wrist corresponding to the back of the user's hand." Ex. 1014 Abstract; *see also* Title ("Wristwatch-Type Human Pulse Wave Sensor Attached On Back Side Of User's Wrist"), ¶[0008] (The "sensor according to the present invention…is worn on the back side of the user's wrist corresponding to the back of the user's hand."), ¶[0009] ("attached on the back side of the user's wrist by a dedicated belt"), ¶[0016] ("worn on the back side of the user's wrist"), ¶[0024] ("[T]he detecting element 2 is stably fixed to the detecting position of the user's wrist" when arranged on the back side of the user's wrist 4.). The only other possible location mentioned for placement of Ohsaki's sensor is "the back side of the user's forearm," which is adjacent to the wrist. Ex. 1014 ¶¶[0016], [0030]. Thus, in my opinion, for these reasons a POSITA would

not have been motivated to use Ohsaki's longitudinal board, which is designed to be worn on the back of a user's wrist, with Aizawa's palm-side sensor.

c) **<u>A POSITA Would Not Have Been Motivated To Eliminate The Identified Benefits Of Aizawa's Flat Adhesive Acrylic Plate By Including A Lens/Protrusion Similar To Ohsaki's Board</u>**

82. Dr. Kenny asserts that a POSITA would have been motivated to modify Aizawa's flat adhesive acrylic plate "to include a lens/protrusion (right), similar to Ohsaki's translucent board 8, so as to improve adhesion between the user's wrist and the sensor's surface, improve detection efficiency, and protect the elements within the sensor housing." Ex. 1003 ¶79. But a POSITA motivated to improve Aizawa's palm-side sensor would not have been motivated to add Ohsaki's convex board. As discussed above, Ohsaki teaches a POSITA that its convex board only provides advantages on the back side of the wrist, in a particular orientation. Ex. 1014 ¶¶[0019], [0025]. Ohsaki further teaches that on the palm side (front side) of the wrist, a sensor with a convex board, "has a tendency to slip off the detecting position of the user's wrist." Ex. 1014 ¶[0023], Figs. 3A-3B.

83. As discussed above, Aizawa teaches that a flat acrylic plate improves adhesion between the sensor and skin on the palm side of the wrist. *See* Sections VII.A.3, VII.B.2.a, above. Taken individually and together, both Ohsaki and Aizawa undermine Dr. Kenny's proposed addition of a convex lens/protrusion

similar to Ohsaki's translucent board to Aizawa's palm-side sensor to improve adhesion. Ex. 1003 ¶79. This is because, as explained above (Sections VII.B.2.a-b): (1) Aizawa teaches a *flat* acrylic plate *improves* adhesion on the wrist's *palm* side; (2) Ohsaki teaches a *convex* board "has a tendency to *slip*" on the wrist's *palm* side. As a result a POSITA reading Aizawa and Ohsaki would have affirmatively avoided modifying Aizawa's flat acrylic plate—which is taught to improve adhesion at Aizawa's sensor location on the palm side of the wrist—with a convex lens/protrusion similar to Ohsaki's convex board because Ohsaki's convex board is taught to slip on the palm side of the wrist where Aizawa's sensor is positioned. The table below summarizes these teachings.

	Front (Palm) Side	**Back Side**
Flat	Flat acrylic plate improves adhesion Ex. 1006 (Aizawa) ¶[0013]; *see also* ¶¶[0026], [0030], [0034], Fig. 1B **(Aizawa's sensor)**	Tends to slip Ex. 1014 (Ohsaki) ¶[0025], Figs. 4A-4B
Convex	Tends to slip Ex. 1014 (Ohsaki) ¶[0023], Figs. 3A-3B	Rectangular convex board prevents slipping Ex. 1014 (Ohsaki) ¶¶[0024]-[0025], Figs. 4A-4B **(Ohsaki's sensor)**

84. Dr. Kenny only considers Ohsaki's discussion of the impact of a convex versus flat surface on the back side of the wrist. *See, e.g.,* Ex. 1003 ¶¶76-84. But a POSITA would have understood that Ohskai's discussion regarding the

85. Based on Aizawa's teaching that a flat acrylic plate improves adhesion on the palm side of the wrist, and Ohsaki's teaching that a convex surface tends to slip on the palm side of the wrist, a POSITA would have come to the opposite conclusion from Dr. Kenny: that modifying Aizawa's "flat cover…to include a lens/protrusion…similar to Ohsaki's translucent board 8" would *not* "improve adhesion." *See, e.g.*, Ex. 1003 ¶79. As discussed above in this section, as well as Section VII.B.2, above, generally, Aizawa and Ohsaki, individually and together rebut Dr. Kenny's assertion that incorporating Ohsaki's convex surface is simply improving Aizawa's transparent plate 6 that has a flat surface "to improve adhesion between the user's wrist and the sensor's surface." Ex. 1003 ¶79. Thus, in my opinion, a POSITA would not have been motivated to modify Aizawa's flat acrylic plate, which improves adhesion at the measurement site on the palm side of the wrist, to include a convex lens/protrusion similar to Ohsaki's board, which tends to slip at the measurement site on the palm side of the wrist.

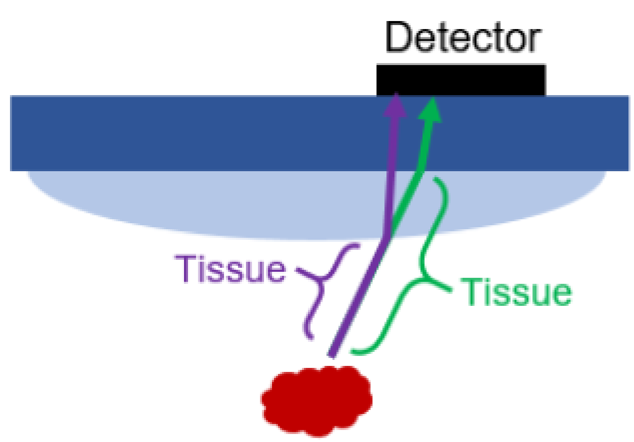
3. A POSITA Would Not Have Been Motivated To Reduce The Measured Optical Signal By Adding A Convex Lens/Protrusion To Aizawa's Sensor

86. Dr. Kenny's proposed combination is also problematic because Dr. Kenny detrimentally modifies Aizawa's flat cover to include a convex "lens/protrusion" positioned over peripheral detectors surrounding a centrally located emitter. Ex. 1003 ¶¶79, 114-115. As discussed below, a POSITA would

have understood that a convex "lens/protrusion" would direct light away from the detectors and thus result in decreased light collection and optical signal strength at the peripheral detectors — not increased signal strength as Dr. Kenny asserts. *See* Ex. 1003 ¶77 (arguing that the convex surface of the translucent board of Ohsaki "increases the strength of the signals").

a) **<u>A POSITA Would Have Understood That A Convex Cover Directs Light To The Center Of The Sensor</u>**

87. Petitioner and Dr. Kenny both admit that a convex cover condenses light passing through it towards the center of the sensor and away from the periphery. Petitioner and Dr. Kenny both illustrated this phenomenon in a petition filed against a related patent. In the Petition in IPR2020-01520 (Ex. 2019), Petitioner explained that a convex cover redirects light coming into the convex surface towards the center, as shown in Petitioner's figure below:



Petitioner's illustration from a related IPR showing that light hitting a convex surface is directed more centrally than light hitting a flat surface (Ex. 2019 at 45)

88. In his declaration in IPR2020-01520 (Ex. 2020), Dr. Kenny likewise confirmed that when using a convex surface, "the incoming light is 'condensed' toward the center." *See, e.g.,* Ex. 2020 at 69-70 (¶119); *see generally* Ex. 2020 69-71 (¶¶118-120), 115-117 (¶¶199-201). Dr. Kenny included the same illustration as Petitioner, which shows light passing through a convex surface is directed more towards the center, as compared to a flat surface. *See, e.g.*, Ex. 2020 at 69-71 (¶118-120).

89. The '366 Patent also confirms these admissions that a convex surface condenses light away from the periphery and towards the sensor's center. Figure 14B (below) "illustrates how light from emitters (not shown) can be focused by the protrusion 605 onto detectors." Ex. 1001 36:3-6. "When the light rays 1420 enter the protrusion 605, the protrusion 605 acts as a lens to refract the rays into rays 1422." Ex. 1001 36:13-15. As shown by Figure 14B of the '366 Patent, the convex shape directs light from the periphery toward the center. Ex. 1001 Fig. 14B.

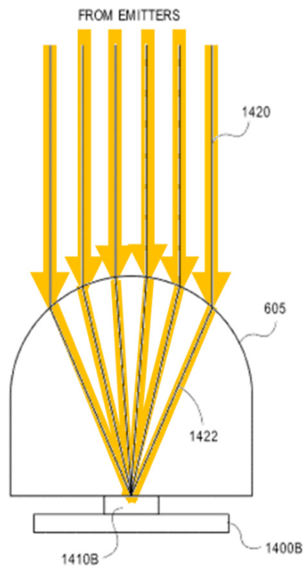


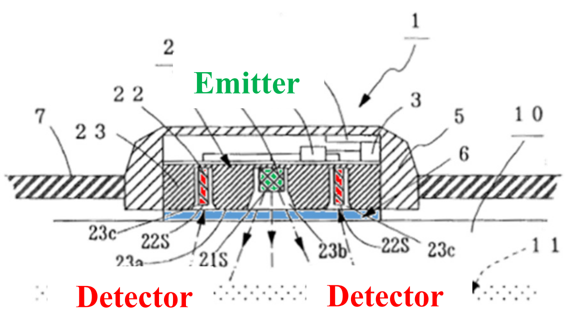
Illustration from the ’366 Patent at issue, showing that light hitting a convex surface is directed towards the center
’366 Patent (Ex. 1001) Fig. 14B (highlighting added to show direction of light)

90. Accordingly, Petitioner, Dr. Kenny, and the ’366 Patent all support that a POSITA would have understood that a convex lens/protrusion would direct incoming light towards the center of the sensor, as compared to a flat surface. In my opinion, a POSITA would have believed that light passing through a convex surface would have been directed to a more central location as compared to light passing through a flat surface. This would have been viewed as a detrimental result because, as discussed in the next section below, Aizawa’s detectors are at the periphery of the sensor.

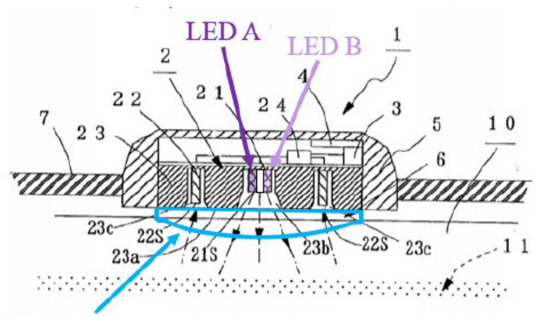
b) **<u>A POSITA Would Not Have Been Motivated To Direct Light Away From Aizawa’s Detectors</u>**

91. Dr. Kenny asserts that a POSITA would have been motivated to modify Aizawa’s flat adhesive acrylic plate with “a lens/protrusion” for improved

detection efficiency. Ex. 1003 ¶79. As illustrated below, Aizawa has peripherally located detectors (in red, below left) and a centrally located emitter (in green, below left) under a flat acrylic adhesive plate (in blue, below left). Ex. 1006 Fig. 1B; *see also, e.g.*, ¶¶[0009], [0026]-[0027], [0033], [0036]. Dr. Kenny's combination introduces a convex "lens/protrusion" (in blue, below right) over Aizawa's peripherally located detectors and centrally located light source (*see, e.g.*, Ex. 1003 ¶79):



Aizawa Fig. 1B (cross-section)
Red: detectors; Green: emitter,
Blue: flat plate

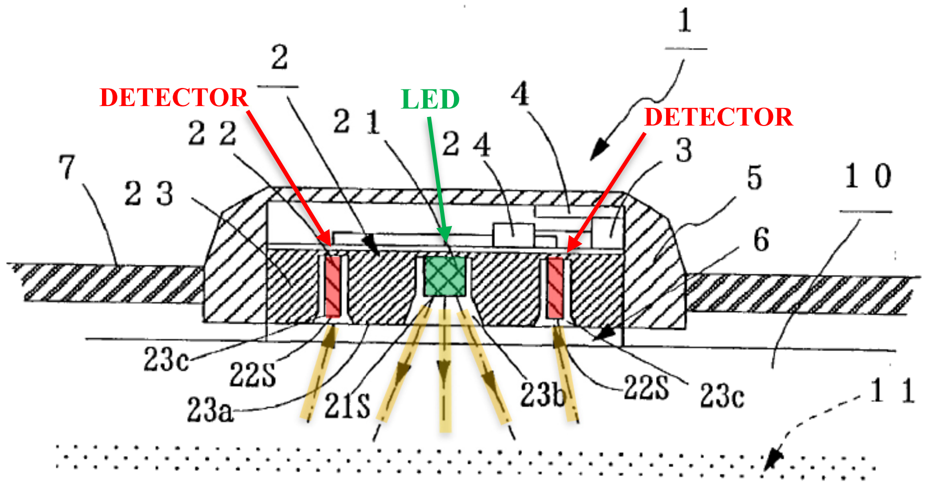


Dr. Kenny's proposed modifications
(Ex. 1003 ¶79)

Aizawa (Ex. 1006 Fig. 2) (color added) (left) versus
Dr. Kenny's proposed combination (Ex. 1003 ¶79) (right)

92. Dr. Kenny asserts that Ohsaki's board "increases the strength of the signals obtainable by Ohsaki's sensor." Ex. 1003 ¶77. However, as discussed above (Section VII.B.3.a), a POSITA would have believed that adding a convex lens/protrusion to Aizawa's flat adhesive acrylic plate would direct light away from the combination's detectors that are located on the periphery. Aizawa

illustrates that the light reaching Aizawa's detectors must travel from the center emitter to the outer periphery of the detectors. Ex. 1006 Fig. 1B, ¶[0027]. Aizawa shows the light path as leaving a single centrally located emitter, passing through the body, and reflecting back to periphery-located detectors (light must travel from the center emitter to the outer periphery to the detectors. Ex. 1006 Fig. 1B, ¶[0027]):



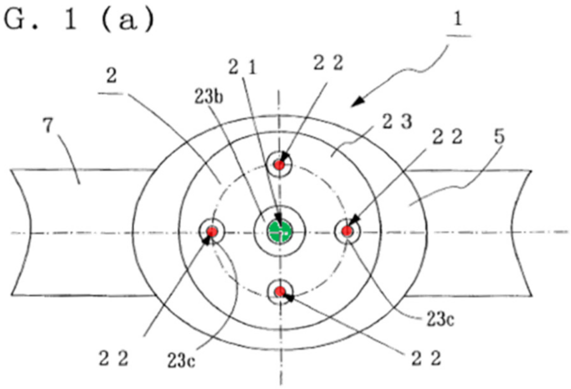
Aizawa Fig. 1B (cross-sectional view, color added)

93. Because of the configuration of Aizawa's sensor, with its central emitter and peripheral detectors, and the illustrated light path that requires light from the central emitter to reach the peripheral detectors, a POSITA would have understood that a change directing light to a more central location would decrease the optical signal at Aizawa's peripheral detectors. Ex. 1006 ¶¶[0026], [0030] (discussing benefits of Aizawa's flat "plate"). Because a POSITA would have believed that adding a convex lens/protrusion would have redirected light to a

more central location as compared to Aizawa's flat adhesive acrylic plate, a POSITA would have concluded that Dr. Kenny's proposed modification would decrease light-collection efficiency at Aizawa's peripheral detectors. Thus, I disagree with Dr. Kenny that a POSITA would have been motivated to modify Aizawa's flat plate to add a lens/protrusion similar to Ohsaki's translucent board based on the belief that it would have improved detection efficiency or otherwise increased signal strength. Ex. 1003 ¶79. As discussed above (Section VII.B.3.a) Dr. Kenny, the Petitioner, and the '366 Patent all support that a POSITA would have believed that adding a convex lens/protrusion would result in the light gathered and refracted to a more central location, and thus away from Aizawa's peripheral detectors, as compared to Aizawa's existing flat plate.

94. In addition, the addition of a convex lens/protrusion similar to Ohsaki's is particularly problematic because both Aizawa and Dr. Kenny's illustration of his combination include small detectors with small openings surrounded by a large amount of opaque material. Ex. 1006 Figs. 1A, 1B, 2; *see, also, e.g.*, Ex. 1003 ¶¶79, 94-98, 100, 112-114 (Dr. Kenny's illustrations). Aizawa's top-down view confirms the detectors' small size. Ex. 1006 Fig. 1A.

FIG. 1 (a)



<u>Aizawa's Features</u>

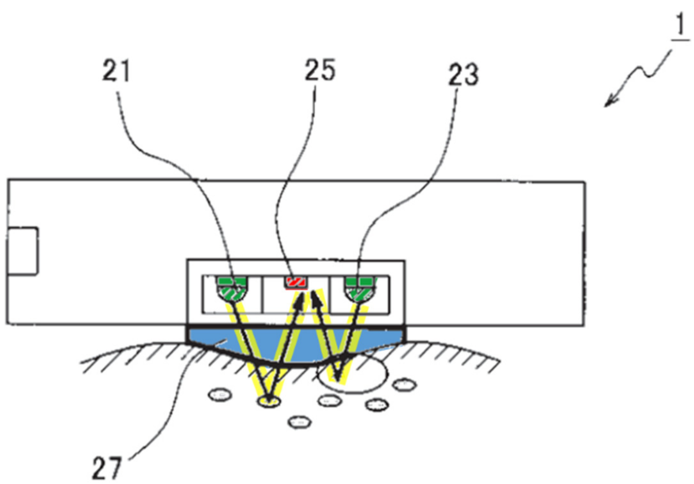
- **Green**: central emitter (21)
- **Red**: peripheral detectors (22)

Aizawa's sensor, showing small detectors (Ex. 1006 Fig. 1A, color added)

95. Thus, Dr. Kenny provides no evidence that a POSITA would have expected a convex lens/protrusion similar to Ohsaki's board to improve detection efficiency at Aizawa's peripheral detectors and increase signal strength. Ex. 1003 ¶¶77, 79. Instead, as explained above (Section VII.B.3.a), a POSITA would have expected that changing Aizawa's flat acrylic plate to a convex lens/protrusion similar to Ohsaki's board would reduce the amount of light gathered and refracted to Aizawa's peripheral detectors. The optical changes resulting from modifying Aizawa's flat surface to include a convex lens/protrusion similar to Ohsaki's board are thus another reason why a POSITA would not have been motivated to make that change.

96. Finally, Dr. Kenny relies on Inokawa for motivation to modify Aizawa's flat surface. Ex. 1003 ¶¶81-84. Dr. Kenny states that Inokawa would provide a "further rationale" (Ex. 1003 ¶81) to add the proposed a "lens/protrusion" (Ex. 1003 ¶79) to Aizawa. Dr. Kenny states that Inokawa

demonstrates "the additional benefit of increasing light collection efficiency, which would in turn lead to an improved signal-to-noise and more reliable pulse detection," based on "refracting/concentrating incoming light signals reflected by the blood." Ex. 1003 ¶82. Unlike Aizawa's circular ring of detectors around a central emitter, Inokawa's sensor is a linear sensor that uses a convex lens (27) to focus light from LEDs (21, 23) positioned on the periphery of the sensor to a single detector (25) in the center. Ex. 1008 ¶[0058], Fig. 2; *see also id.* ¶[0015] ("This lens makes it possible to increase the light-gathering ability of the LED as well as to protect the LED or PD.").



<u>Inokawa's Features</u>

- **Green**: peripheral emitters (21, 23)
- **Red**: central detector (25)
- **Blue**: convex lens (27)
- Arrows showing the direction of light in original, highlighting in yellow added

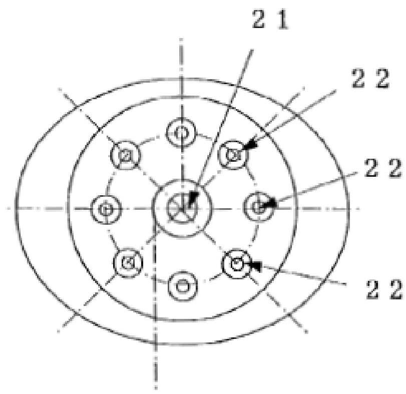
Inokawa Fig. 2 (color added)

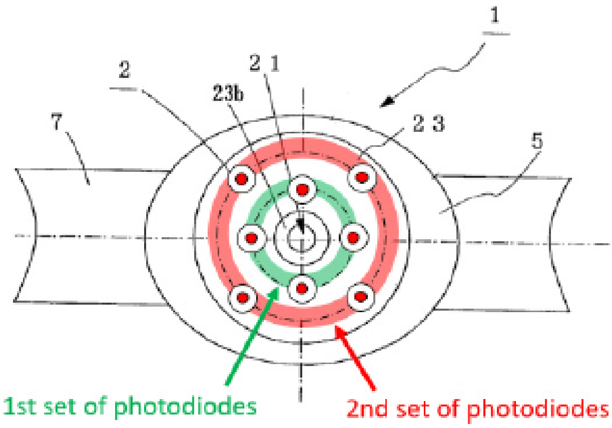
97. As illustrated above, Inokawa's linear detector-emitter configuration is different from Aizawa's circular detector arrangement. In Inokawa's sensor, light from Inokawa's periphery-located LEDs will reflect off the body and pass through the lens, which directs incoming light to the centrally located detector.

Ex. 1008 ¶[0058]. Inokawa's convex surface thus concentrates incoming light towards the sensor's center, where the detector is located, and away from the periphery. In contrast, Aizawa's detectors are not located at the center—they surround the central emitter. Inokawa would thus have further demonstrated to a POSITA that the proposed combination would decrease light gathering at Aizawa's peripheral detectors, which is the opposite of Dr. Kenny's motivation to combine. Ex. 1003 ¶82.

4. A POSITA Would Not Have Selected A Convex Cover To Protect The Sensor's Optical Elements

98. Dr. Kenny also asserts that a POSITA would have been motivated "to modify the [Aizawa] sensor's flat cover…to include a lens/protrusion…similar to Ohsaki's translucent board 8, so as to…protect the elements within the sensor housing." Ex. 1003 ¶79. As illustrated below, Aizawa already includes a flat adhesive acrylic plate (blue) that protects the elements (emitter, detectors) within the sensor housing. Ex. 1006 Fig. 1B; *see also, e.g.*, ¶¶[0023]-[0026], [0030]. Thus, in my opinion, a POSITA would not have been motivated to modify Aizawa's existing flat adhesive acrylic plate to add a convex lens/protrusion similar to Ohsaki's board for protection because a POSITA would have understood that Aizawa's flat cover already protects the sensor's components. Ex. 1006 Fig. 1B; *see also, e.g.*, ¶¶[0023]-[0026], [0030]. Dr. Kenny asserts that the convex lens/protrusion "protect[s] the elements within the sensor housing" (Ex.





Aizawa Fig. 4A Dr. Kenny's Proposed Combination (Ex. 1003 ¶73)

108. Dr. Kenny does not give a plausible reason why a POSITA would have been motivated to modify Aizawa's structure and add a second ring of four detectors that is farther from the emitter. Dr. Kenny's suggestion is contrary to Aizawa's illustrated embodiment, which demonstrates that eight detectors readily fit into the existing ring, and assumes adding a second ring of four detectors that is farther from the emitter would have some benefit. Ex. 1003 ¶¶72-75. But Mendelson 2003 adds a second ring of detectors farther away from the emitter because there is no room for more detectors in the existing ring. Ex. 1024 Fig. 1. The proposed new "outer" ring of detectors is not needed in Aizawa, and a POSITA would have understood that Dr. Kenny's new outer ring would have received substantially lower light intensity and required relatively greater power consumption to use than additional detectors added to the "inner" ring. *See* Ex. 1024 at 4 (stating optical signal "is inversely related to the separation distance between the PD and the LEDs" and outer ring detectors require LEDs

"significantly higher currents"). A POSITA would have believed the proposed modification would result in greater power consumption as compared to Aizawa's existing 8-detector structure, all placed on the inner ring closer to the detector. This is particularly true because Dr. Kenny also proposes adding a convex cover that would direct light away from the outer ring of periphery-located detectors. *See* Sections VII.B.1-3, above. A POSITA motivated to achieve improved power savings—Dr. Kenny's stated motivation for his modification (Ex. 1003 ¶72)—would not have added an outer ring of detectors to Aizawa, and instead would have added detectors to Aizawa's existing ring as disclosed in Aizawa's already disclosed 8-detector embodiment that positions all eight detectors in a single concentric circle.

109. Dr. Kenny's proposed modification thus changes Aizawa's structure in a way that Mendelson 2003 itself indicates would result in relatively worse power consumption (Ex. 1024 at 4) compared to Aizawa's existing configuration. In my opinion, a POSITA seeking to increase the number of detectors would have implemented Aizawa's existing eight detector arrangement, and not come up with an entirely new configuration with multiple rings of detectors.